An analysis of Quality Culture and Quality Management Practices in selected South African pharmaceutical organisations

Submitted in fulfilment of requirements of the degree of Doctor of Philosophy: Quality Management in the Faculty of Management Sciences at the Durban University of Technology.

Bronwyn Claudia Swartz

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Supervisor: _____

Prof Shalini Singh

Abstract

South African pharmaceutical organisations struggle to compete with their counterparts in other countries. To overcome this challenge, a suitable Operational Excellence (OpEx) strategy in their manufacturing environment can improve the quality of pharmaceutical products and encourage economic growth in South Africa. This study examined the contribution of a Quality Culture on OpEx in selected pharmaceutical organisations. The objective of this study was to develop a conceptual Model of Quality Management Practices supported by Quality Culture, for Category A pharmaceutical manufacturers in the South African Pharmaceutical Industry, to promote OpEx.

This study followed a two-phase sequential embedded mixed method approach. Statistical results were derived from the analysis of quantitative data from a questionnaire which used a census sample. Thereafter, a qualitative phase included an in-depth exploration of a smaller purposefully selected sample of individuals. The sample size of the pilot study was one manufacturer while the main study target population consisted of 30 pharmaceutical manufacturers.

Internal validity (reliability) was assured by Cronbach's alpha in the quantitative phase for both the pilot and main study. External validity was assured through the use of a standard instrument in the pilot study and main study. Data saturation and peer review assured validity in the qualitative phase of the pilot and main study. Ethical clearance for this study was granted through DUT's institutional channels.

Results of the quantitative phase of the main study (n=17, response rate 57%) found a significant regression relationship (68%) between successful Quality Management Practices and the Quality Culture in pharmaceutical organisations. Quantitative analysis statistically confirmed the suitability of OpEx dimensions for the Model and established a correlation between these OpEx dimensions and four important organisational culture types namely: clan culture, hierarchical culture, adhocracy culture and market-driven culture. Results of qualitative data analysis (n=3) indicated that an appropriate blend of culture types supports OpEx in the South African pharmaceutical industry. Based on these findings, an OpEx

Model was developed for South African pharmaceutical manufacturers. This study recommends that the OpEx model be adopted by South African pharmaceutical manufacturers to cultivate an appropriate blend of organisational culture types, within their overall Quality Culture. This will support and enable effective Quality Management Practices and OpEx. A limitation of the SA Pharma OpEx Model developed was that it lacked a financial component. Future research should include the financial component to expand on the SA Pharma OpEx Model.

Keywords: Quality Culture, Operational Excellence (OpEx), Quality Management Practices, South African Pharmaceutical Industry

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Declaration

I, Bronwyn Claudia Swartz, hereby declare that this thesis is wholly my own work and that all the references to the best of my knowledge, are accurately reported. This work has not been submitted for a degree at any other university.

28 January 2019

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Signature Date

Dedication

This study is dedicated to Joshua and Micaiah, for three decades of love.

One day when I am big, I'm going to be like them.

Acknowledgements

"*If I have seen further it is by standing on the shoulders of Giants.*"

- Sir Isaac Newton in 1675

My deepest gratitude to my giants…

- *Thank you **My Jesus***. Thank you.
- *Thank you, **Mummy and Daddy***. Finishing this would have been impossible without your unconditional love and support. I love you.
- *Thank you, **Shalini**,* for being an unwavering beacon of light, constantly pointing the way. Bless you.
- *Thank you to **all my students**.* You are all my greatest teachers and my true motivation to push myself beyond what I believe my limit is. Thank you.

Abbreviations and Terminology

Within this thesis various abbreviations associated with the pharmaceutical industry as outlined below are used:

Abbreviations

FDA	United States Food and Drug Administration
GMP	Good Manufacturing Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
MCC	Medicines Control Council
NRA	National Regulatory Authority
OpEx	Operational Excellence
SAHPRA	South African Health Products Regulatory Authority
WHO	World Health Organisation

Terminology

1) **Corrective Action and Preventive Action**: Corrective and Preventive action consists of improvements to an organisation's processes taken to eliminate causes of non-conformities or other undesirable situations. Corrective Action is remedial action to remedy a non-conformity. Preventative Action is action to prevent the conformity from taking place again.
2) **Deviation**: A deviation is a departure from the approved procedure or established standard or specification during pharmaceutical manufacturing.
3) **MCC:** The regulatory body responsible for determining which medicines can be sold in South Africa (SA). The MCC governs the manufacture, sale and distribution of medicines in SA.
4) **Pharmaceutical Manufacturer**: An independent organisation that is involved in developing manufacturing, packing and distribution of registered medicines.

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CHAPTER ONE
ORIENTATION OF THE STUDY

'Learning is not compulsory, ...neither is survival.'

- Dr William Edward Deming

Operational Excellence (OpEx) in the South African pharmaceutical manufacturing milieu is regarded as a critical factor for determining the quality of healthcare in South Africa. According to Ndenze (2017), Dr Anban Pillay, deputy-director of regulation and compliance in the South African Department of Health, stated that South African pharmaceutical organisations struggle to compete with their counterparts in other countries. South African pharmaceutical organisations need to increase their productivity, reduce their costs, tap into potential emerging markets and switch from selling medicines to managing quality to improve their manufacturing operations and thereby their outcomes.

Pioneers in research on quality management in the pharmaceutical industry, Friedli and Gronauer (2010) argue that quality management is the cornerstone of every effective internationally recognised OpEx Model. This exploratory doctoral study examines Quality Management Practices used in pharmaceutical organisations from a Quality Culture perspective, to design a suitable conceptual OpEx Model bolstered by Quality Culture for the South African pharmaceutical industry. In so doing, this study undertakes to close the gap highlighted by Ndenze (2017) above, by offering industry practical guidance that moves beyond proposing Quality Management Practices which are to be included in the conceptual OpEx Model. This study also investigates the manner in which Quality Culture supports selected Quality Management Practices which ultimately leads to OpEx.

1.1 Background and context of the study

According to Snyder (2014) and Calnan (2013), the global pharmaceutical industry is a dynamic business environment. Acquisitions and mergers, operational realignment, portfolio changes, manufacturing relocation, facility repurposing and organisational restructuring and integration are common

activities used by pharmaceutical organisations to increase stakeholder value. However, research (Friedli and Bellm 2013b; Woodcock 2012) suggests that none of the above-mentioned activities has been successful in the pursuit of superior sustainable performance for pharmaceutical organisations. Instead, it is thought that sustainable improvement of pharmaceutical manufacturing operations requires a balanced system approach to ensure that organisations stay efficient, effective, competitive and relevant to the markets that they service (Friedli and Bellm 2013a).

Friedli and Basu (2013) proposed that an OpEx strategy be employed to achieve an excellent standard of operations in pharmaceutical manufacturing. They regarded such a strategy as a competitive weapon which leads to superior performance in the global pharmaceutical industry. This entails the adoption of Quality Management Practices which enables an organisation to continuously improve itself across all dimensions (Friedli, Mänder and Bellm 2013; Coffey 2008). A nuanced characteristic that must, however, also be taken into account in the pharmaceutical industry, is the very heavily regulated environment. Meagher (2006) elaborates on this, explaining that in this onerous regulatory environment, Quality Management Practices not only improve operations but also enables compliance with regulation. Empirically his research establishes a strong correlation between Quality Management Practices and regulatory practices, and he notes specific aspects of this interdependent relationship to improve market share, competitiveness and performance in pharmaceutical organisations.

Against this backdrop, Jimenez Aquino and Husman (2008), agree that mere compliance with the minimum statutory quality management requirements is not enough for organisational prosperity in the global pharmaceutical industry. They argue that while compliance is critically essential, a compliance-based approach to quality management is reactive and rigid. This approach fails to account for the fluid and dynamic nature of pharmaceutical manufacturing operations, and thus its applicability and effectiveness is limited. According to Malhi (2013), Friedli, Basu, Gronauer and Werani (2010) and Coffey (2008), a better approach than a reactive approach, is to focus on ‘people’ in the pharmaceutical

organisation instead since ‘people’ design, operate, improve and re-invent activities, processes, systems and structures in organisations. These authors imply that employees of a pharmaceutical organisation represent the differentiating factors that provide an organisation with the ability to overcome inertia and are the key to organisational success and excellence.

Malhi (2013) asserts that when an organisation’s employees share values which promote quality management, that organisation possesses a Quality Culture. Values are principles that are held in high regard, for example, ‘the customer is important’, ‘sharing information is important’ or ‘employee autonomy is important’. This shared importance drives normal behaviour in the organisation and becomes social cooperation. From Malhi’s (2013) perspective, when quality management is valued by employees in a pharmaceutical organisation, the culture of that organisation will direct organisational behaviour towards sustaining superior Quality Management Practices, and, by implication, performance excellence. Raghavendra, Chauhan and Mallikarjuna Rao (2017) challenge this position on Quality Culture by suggesting that shared values originate from organisational behaviour related to quality management. They do, however, hold the same view as Malhi (2013) on Quality Culture and Quality Management Practices being correlated with organisational performance. Thus, it can be inferred that a middle ground emerges which suggests that Quality Culture has a cyclical nature between shared values and behaviour, as depicted in Figure 1.1.

Figure 1.1 The cyclical nature of Quality Culture (Developed by the Researcher)

This research sets out to analyse Quality Management Practices in relation to the Quality Culture of South African pharmaceutical manufacturing organisations to determine if this relationship is a key constituent for success in pharmaceutical organisations.

1.2 Pharmaceutical regulation in South Africa

The South African pharmaceutical industry is guided by regulation imposed regarding the Medicines and Related Substances Control Act 101 (South Africa 1965). Statutory controls set out in the Act above are currently enforced by the South African Health Products Regulatory Authority (SAHPRA), which was established in June 2017. The previous name for the regulatory authority was the Medicines Control Council (MCC). The reason for the name change was due to the expansion of the scope of the authority, to include medical devices, in-vitro diagnostics and aspects of radiation control, in addition to medicines. The Department of Health (2018) explains that the Medicines and Related Substances Act, 1965 (Act 101 of 1965) was amended by Act 72 of 2008, together with Act 14 of 2015, which led to the establishment of SAHPRA. At the time that this research study commenced, the MCC was the only applicable name of the regulatory authority. In terms of the scope of this research, the role and function of the regulatory authority have not changed. Thus, this study refers to the MCC since it was the name of the regulatory authority at the time that the majority of this research was conducted.

The statutory power of the MCC includes the authority to grant or refuse permission for a medicine to be marketed in South Africa. It governs manufacture, sale and distribution of medicines in South Africa. The Medicines and Related Substances Control Act 101 (South Africa 1965) lists the following basic categories of medicines that are regulated:

- Category A includes medicines that are intended for human use and which are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

- Category B includes medicines which cannot normally be administered without further manipulation;
- Category C includes medicines intended for veterinary use which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.
- Category D includes medicines that are traditionally regarded as complementary medicines, such as vitamins and homeopathic medicines.

The manufacture of Category A medicines in a Good Manufacturing Practice (GMP) licenced facility is the only category of concern to this research study.

MCC has adopted the Good Manufacturing Practice (GMP) guidelines as the minimum acceptable standard for granting a pharmaceutical organisation authorisation to manufacture and market any pharmaceutical product in South Africa. Although a number of distinguishable GMP guidelines have been published internationally, all the guidelines are based on the World Health Organisation (WHO) GMP guideline (World Health Organisation 2014) and all are geared toward providing insight into commonly accepted principles of quality assurance within the pharmaceutical industry and relevant international regulatory authorities (Haleem, Salem, Fatahallah and Abdelfattah 2014).

Quality strategies are employed by pharmaceutical manufacturing organisations in an attempt to comply with GMP (Mostafa 2014; Medicines Control Council 2010) and achieve superior business performance. This thesis examines these quality strategies relative to Quality Culture to establish the extent to which cultural influences play a role in the successful implementation of these strategies. Through the identification of cultural characteristics that support these practices, it is deemed possible to select the best practices for inclusion into a uniquely South African OpEx Model.

1.3 Statement of the problem

The legacy of historical inequality in South Africa is still very evident in the pharmaceutical industry. According to Henderson (2016), the fundamentally disproportioned two-tiered South African healthcare system is evidence of this.

She argues that most stakeholders in the industry will agree that the current state of healthcare is not only unjust but also not sustainable for any country's economy and wellbeing. Thus, South African pharmaceutical organisations must seek ways to improve their manufacturing practices.

Henderson (2016) believes that, in some respects, the healthcare industry is successful as it is the largest in Sub-Sahara Africa and has a world-class private sector that is on par with any developed country on the globe. However, in other respects, efforts have fallen significantly short, given the nation's heavily overburdened public healthcare system which caters to the vast majority of the population who still lack fluid access to basic medicines.

Foregrounded by the commentary above, Henderson (2016) suggests that if operations in pharmaceutical manufacturing are to improve, the state of Health Care in South Africa will concomitantly improve. The analysis of Quality Culture and Quality Management Practices in selected South African pharmaceutical organisations is, therefore, required, to provide information necessary to develop a Model of the most appropriate practices for inclusion in a conceptual OpEx Model suitable for the South African pharmaceutical industry. Hence, the formulated problem statement of this study is 'The dearth of knowledge on the impact of Quality Culture on manufacturing practices, however, inhibits South African pharmaceutical manufacturing organisations from selecting the most suitable Quality Management Practices for inclusion in a conceptual OpEx Model'.

1.4 The research aim

This research sets out to analyse the effect of Quality Culture on Quality Management Practices in pharmaceutical manufacturing organisations as part of an endeavour to secure OpEx for organisations. Studies (Keeling, Rutten and Telpis 2017; Federation of Indian Chambers of Commerce and Industry 2017) found that there is a link between Quality Culture and quality outcomes in the global pharmaceutical industry and that organisations with a stronger Quality Culture have better overall operational outcomes in general.

1.5 The research objectives

The objectives of this study are as follows:

- Through the evaluation of literature, identify the most common Quality Management Practices to support business performance and regulatory requirements in the pharmaceutical industry.
- Conduct an explorative literature study on OpEx strategies used in the global pharmaceutical industry.
- Perform a literature examination on three founder member regulatory authorities of the International Council for Harmonisation (ICH) namely, Japan, Europe and the United States.
- Conduct a study on Quality Management Practices, based on data collected from selected manufacturers of Category A medicines in the pharmaceutical industry in South Africa.
- Develop a conceptual Model of Quality Management Practices supported by Quality Culture for Category A manufacturers in the South African Pharmaceutical Industry that promotes OpEx in alignment with the MCC (2010) Guide to GMP.

1.6 Rationale of the study

An industry Report DuPont (2014) maintains that an OpEx strategy provides an organisation with the benefits of lower costs, increased efficiencies, fewer injuries, maximum sustainable returns on operating assets and an enhanced competitive global position. At present, there is no conceptual OpEx Model that takes Quality Culture into account, available for pharmaceutical organisations in South Africa. The motivation behind this study is to provide South African pharmaceutical organisations with a quality tool (a conceptual OpEx Model of Quality Management Practices based on Quality Culture) which will enable them to elevate their global status regarding quality management and manufacturing excellence.

1.7 Theoretical framework

Proponents of quality management (Martz 2017; Oakland 2014; Kovach and Mairani 2012) report that worldwide, approximately 70% of all newly deployed quality management initiatives fail. Gambi, Gerolamo and Carpinetti (2013) suggest that the reason for this high failure rate is that not all quality management initiatives are universally applicable. Failure occurs when the impact of contextual variables on a quality initiative in a particular environment is not properly understood at the time of deployment. Thus, brief outlines of the theoretical concepts regarded as influential, as well as important contextual variables to this study, follow below. Concepts are 'quality management: the relationship between culture, practices, climate and operational performance' and 'performance frameworks for quality management', as well as 'regulation in the pharmaceutical industry'. A detailed discussion on each of these concepts will follow in Chapters Two and Three, and their contributions to the development of the Model in this study will be duly considered in a comparative study presented in Chapter Four.

1.7.1 Quality management: Relationship between culture, practices, climate and operational performance in the pharmaceutical industry

Malhi (2013) asserts that an organisation self-regulates on the basis of the shared values of that organisation. This implies that the steering role of Quality Culture is fundamentally important to an organisation. McNabb and Sepic (1995) argue that the receptiveness to quality management initiatives in an organisation is influenced by the Quality Culture and climate of the organisation. They propose that Quality Culture is a contextual variable in quality management and a precursor for success.

Research proves that, if quality principles are held in high regard, the behaviour associated with quality management will be affected. Similarly, Gambi, Gerolamo, and Carpinetti (2013) and Projago and McDermott (2005) also yielded consistent findings. They found that Quality Culture and climate during quality management influenced operational performance during manufacturing. The

theories mentioned above provide this study with guidance on organisational culture and climate in the context of quality management.

An explanation of climate in the context of quality management, offered in the seminal findings of McNabb and Sepic (1995) is that climate emerges from the interaction of people within a group and is loosely based on the underlying culture of an organisation. They propose that the climate in an organisation may be analogous to culture. However, the climate during quality management is more prone to distortion than culture, due to the qualities and abilities of individuals in a particular group. Climate is thus more susceptible to change and more readily altered than Quality Culture, although both originate from shared values in an organisation.

Analogous views indicating that culture and climate have an impact on the behaviour of the people in the group were noted from Schneider and Barbera (2014), Ashkanasy, Wilderom and Petersen (2010), Emery, Summers and Surak (1996) and McNabb and Sepic (1995). They regard climate as a narrower concept than culture and suggest that culture goes deeper than the immediate environment. Leading studies on Quality Culture (Patterson, Warr and West 2004; Kopelman, Brief and Guzzo 1990) returned that Quality Culture is a product of assumptions based on the historical management of quality in an organisation and climate is a function of that culture. Thus climate is how people perceive the management of quality in the present. This coincides with Malhi's (2013) view, mentioned earlier.

The theory above provides this study with three important conceptual lenses with which to examine Quality Management Practices in South African pharmaceutical organisations. The three lenses are 'Quality Management Practices', 'Quality Culture' and the 'Climate during the management of quality' which are all believed to influence operational performance. A growing body of empirical research suggests that a direct relationship exists between strategically deployed quality management and improved organisational performance (Friedli and Basu 2013; Friedli and Bellm 2013a; Gharakhani, Rahmati, Farrokhi, and Farahmandian 2013; Knapp 2010 and Coffey 2008), Thus this research sets out to examine this

relationship, thereby laying the foundation for the development of a Model of Quality Management Practices to improve operational performance.

1.7.2 Performance frameworks for quality management

The usefulness of international quality award criteria as guiding framework during quality model development is promoted by Alonso-Almeida and Fuentes-Frías (2012), Westcott (2013) and Vokurka, Stading and Brazeal (2000). In accordance with this, a global trend emerges whereby various models consisting of a selection of Quality Management Practices based on quality award criteria have been conceived, such as the Japanese Deming Prize (DP), the United States Malcolm Baldridge National Quality Award (MBNQA), and the European Foundation for Quality Management Award (EFQMA) in Europe. The foundation of the trend is the belief that there is a positive relationship which exists between effective quality management initiatives and superior operational performance at pharmaceutical organisations (Friedli and Bellm 2013a; Werani, Pfahlert, Reimers, and Diederich 2013 and Coffey 2008).

There are significant similarities in the criteria used by these various international quality awards (Alonso-Almeida and Fuentes-Frías 2012; Vokurka, Stading and Brazeal 2000; Bohoris 1995). This suggests that a Model based on quality award criteria can be developed for the pharmaceutical industry in South Africa, which will enable the assessment of the level of operational excellence achieved by organisations and ensure compliance to regulation.

1.7.3 Regulation in the pharmaceutical industry

Research on pharmaceutical manufacturing (Woodcock 2012; Rägo and Santoso 2008; Patel and Chotai 2008) indicates that quality management in this industry is explicitly distinguishable from commercial product manufacturing, on the basis of the stringent regulatory requirements which indiscriminately apply to each aspect of the manufacturing process for all pharmaceutical manufacturers, globally. Failure to comply with all Government mandated regulation in any part of the pharmaceutical manufacturing process is a punishable offence, resulting in a fine and possibly a custodial sentence for the person or organisation

responsible for the failure (International Society for Pharmaceutical Engineers 2017; Seshadri 2015).

Globally, the most commonly used quality management standard which constitutes the substructure of pharmaceutical regulation is GMP (Haleem *et al*. 2014), and is, therefore, discussed in detail in Chapter Three of this study. Jacobs and Signore (2016), DeRoo (2014) and Patel and Chotai (2008) highlight a direct link between the development of legislation and poor quality management during pharmaceutical production. From this, it can be gleaned that a comprehensive understanding of GMP is essential in developing a conceptual OpEx Model for pharmaceutical manufacturers as the Model needs to be nested within the parameters of GMP. The agreement was noted between numerous literature sources (Lienbacher and Karner 2017; Calabrese, Trotter and Foo 2016; Haleem *et al*. 2014; Jacob 2013; Woodcock 2012; O'Donnell 2008) on the most common Quality Management Practices used during pharmaceutical manufacturing. These authors confirm conformity of all of the individual Quality Management Practices mentioned with the requirements of GMP, and Haleem *et al.* (2014) particularly emphasise the holistic application of regulated Quality Management Practices within a Quality Strategy. This research will, therefore, explore those Quality Management Practices and strategies from a Quality Culture perspective.

1.8 Research design and methodology

A mixed methods research approach is adopted to manage this explorative study of the impact of Quality Culture on Quality Management Practices during pharmaceutical manufacturing. Hesse-Bieber (2010) describes mixed methods research as the systematic integration of quantitative research and qualitative research into a single investigation and claims it is suited to managing a complex exploration and supporting model development. For model design, the research approach relies on the review of the literature to qualitatively explore quality management in the global pharmaceutical industry. However, it also makes use of an empirical quantitative investigation (questionnaire) to evaluate South African industry practices. Following the initial quantitative data analysis, a Model

will be designed. The design of the Model is then qualitatively evaluated using interview data to refine the Model.

The target population of this study consists of 32 Category A pharmaceutical manufacturers with current MCC licences, in South Africa. Due to the small size of the target population of this study, a census sample for the quantitative component of the main study was adopted. Prior to the main study, a pilot study to review the concepts will be undertaken, to detect possible flaws in the research instrument. Due to the small size of the target population, specialist biological product and enzyme manufacturer that is not part of the target population but operates under the same conditions and regulatory requirements was selected as the sample in the pilot study. This was based on the recommendation of Vogel and Draper-Rodi (2017), that the pilot study data is not be used in the main study. The final research instrument will be prepared once the pilot study is concluded.

In the main study, three organisations did not respond to any requests for data. Twelve organisations declined invitations to take part in this study. Consequently, quantitative research data was collected from the seventeen remaining organisations in the target population. Triangulation is employed by this researcher, and the findings of the questionnaire data and literature are used to develop a Model.

1.9 Data collection and analysis

The data collection instrument that will be adopted by this study is presented in Table 1.1 and discussed in greater detail in Chapter Five.

Table 1.1 Population and Sampling (Developed by the Researcher)

	Chapter	**Description**
Qualitative Research (Phase 1) Inductive	Chapter 4	Literature examination - Comparative study compares the pharmaceutical industry in Japan, Europe and the United States
Quantitative Research Deductive	Chapter 6	Two questionnaires form a single quantitative data collection instrument Part 1 has four sections which collect demographic information from research participants, data on Quality Management Practices, data on Quality Culture and data on quality climate Part 2 is an adaptation of a standard data collection instrument designed by Cameron and Quinn (2011) and was validated by Heritage, Pollock and Roberts (2014)
Mixing in an embedded design based on a description provided by Plano Clark, Huddleston-Casas, Churchill, O' Neil and Garrett (2008)		
Qualitative Research (Phase 2) Inductive	Chapter 7	Semi-structured interviews

1.9.1 Quantitative data collection and analysis

The questionnaire that will be disseminated to the target population of this study will consist of two parts. The first part of the questionnaire elicits responses from South African pharmaceutical organisations on their Quality Culture, Quality Management Practices and climate during quality management. The second part of the questionnaire is a customised instrument adapted by the researcher and is based on the literature study. The second part of the questionnaire elicits responses from organisations on their Quality Culture based organisational culture assessment instrument (OCAI), which was developed by Cameron and Quinn (2011) and adapted for this research study. Four employees from each organisation were requested to complete both parts of the questionnaire. Statistical analysis of quantitative data took place using IBM SPSS (Version 25®) software.

1.9.2 Qualitative data collection and analysis

Two phases of qualitative data collection and analysis take place in this study. The first phase entails the collection and analysis of the literature on Quality Management Practices in the global pharmaceutical industry. Findings from the first phase of qualitative data analysis are compared to findings from the quantitative data analysis. These will be considered in the design of a Model of conceptual Quality Management Practices supported by Quality Culture, for use by South African pharmaceutical organisations in securing OpEx.

During the second phase of qualitative data collection, interview data is collected from a purposely non-probability sample of three pharmaceutical organisations. Participants are selected on the basis of significant findings obtained from quantitative data analysis. Thematic data analysis of this qualitative data took place using ATLAS.ti (Version 8.0.43®) software. The purpose of the second phase of qualitative data collection and analysis is to refine the design of the Model.

1.10 Ethics

Ethical clearance was obtained from the Durban University of Technology (DUT), and this research was conducted in accordance with DUT's Research Ethics Policy and Guidelines. Both the pilot and main study participants signed an informed consent form and were told that participation in this study was voluntary. Anonymity and confidentiality of participants were protected as research questionnaires did not require names. Interviews data was anonymised by the researcher during transcription.

1.11 Research assumptions

The assumptions made in this research are that:

- All research participants and respondents have sufficient knowledge and experience of quality management systems in their respective roles within the pharmaceutical organisation they represent.

- All research participants will be honest, objective and comfortable when providing answers to the questionnaire and answering interview questions.
- The study of the literature will provide the researcher with the necessary insight to develop a South African conceptual OpEx Model for pharmaceutical organisations and contribute to the current body of knowledge within the industry.

1.12 Research constraints

Bazely (2017) refers to research constraints as uncontrollable events that may interfere with the results of the study. These restrictions are related to potential weaknesses and define the scope of a project.

1.12.1 Delimitations

- Only current Category A pharmaceutical manufacturers with a current GMP licence in South Africa, at the time of data collection, are considered as a participant-organisation of this research.
- In this study, unless explicitly stated otherwise, references to ‘culture’ and ‘climate’ are to be interpreted at Quality Culture (the culture of an organisation pertaining to quality management) and climate during quality management.

1.12.2 Limitations

- The lack of availability of research participants who could participate in this study due to other organisational, operational demands is a limitation to the Researcher’s ability to collect data.
- The proposed conceptual Model might not replace any organisational Quality Management Practices already in use.

1.13 Chapter outline and content analysis

The following is a brief outline of the chapters of this thesis:

- Chapter Two presents a review of the literature on the relationship between quality management and OpEx. It then highlights the association between

Quality Culture, the climate of an organisation during quality management and OpEx. The chapter then turns toward the evaluation of global quality award criteria for guidance on the design of a conceptual OpEx Model for the pharmaceutical industry.

- Chapter Three introduces theoretical knowledge on mandatory regulation in the global pharmaceutical industry, including reasons for promulgation of GMP. It details the structure of this important quality management standard and discusses the most common global Quality Management Practices that can be used in the South African pharmaceutical industry in order to comply with GMP.
- Chapter Four uses activity theory to report on the three-member countries who comprise the original International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) cultural tripartite, namely Japan, the United States and Europe, in a comparative study. This comparative study examines the cultural attributes of each tripartite member that influences pharmaceutical manufacturing.
- Chapter Five describes the mixed methods research design and methodology that is employed by this study. The pilot study is reviewed, and the main study is introduced.
- Guided by the conceptual framework, Chapter Six analyses data obtained from South African pharmaceutical organisations. Through the consolidation of findings from the literature reviewed in Chapter Two, Three and Four and data analysis, this chapter renders the profile of Category A pharmaceutical manufacturers in South Africa in terms of Quality Culture, Quality Management Practices and Climate during quality management.
- Chapter Seven synthesises the findings of Chapter Six with the literature on award criteria presented in Chapter Two and is used to develop the proposed Model. The Model is presented and then optimised through qualitative data analysis this chapter.
- Chapter Eight is the final chapter, in which an overall summation of research is performed. This chapter identifies the limitations of this research and considers future directions for further study.

1.14 Chapter summary

The chapter outlined the thoughts of global researchers who contend that pharmaceutical organisations all over the world are facing a new reality, where OpEx is a requirement for survival in the global industry. A plethora of Quality Management Practices has arisen within the confines of regulation in an attempt to do so. There is, however, significant evidence that suggests that the differentiating factor for success is Quality Culture. The following chapter evaluates the relationship between 'Quality Management Practices', 'Quality Culture' and 'Operational Performance' in the highly regulated pharmaceutical industry.

CHAPTER TWO
OPERATIONAL EXCELLENCE AND QUALITY CULTURE

'Quality is everyone's responsibility.'

- Dr William Edward Deming

Advancing from a conclusion drawn in Chapter One, that approximately 70% of all new quality management initiatives are unsuccessful, this chapter embarks on an exploration of possible attributing factors for this. Guided by previous studies (Gambi, Gerolamo and Carpinetti 2013; Rad 2006; Projogo and McDermott 2005) which found that Quality Culture during quality management significantly influences operational performance during manufacturing, this chapter evaluates the relationship between 'Quality Management Practices', 'Quality Culture' and 'Operational Performance' in the highly regulated pharmaceutical industry.

This chapter is structured into two main sections, each of which is then subdivided into smaller sections exploring different topics under the high-level theme of that section. The theme of the first section is Quality Culture. The relationship between quality management and organisational culture is discussed before the concepts of Quality Culture and Quality Climate are defined. Thereafter, competing values of organisational culture are discussed.

The theme of the second section pertains to performance frameworks associated with quality management. The three most widely known international quality awards are theoretically scrutinised, to identify the elements within them that conceptual OpEx Models are required to have. This section concludes with a comparative synopsis of the common and most significant features of the three quality awards which will be used to inform the design of the Model being developed in this study. The chapter ends with a chapter summary.

2.1 Culture during Quality Management for excellence in operations

Seminal work of Hildebrandt, Kristensen, Kanji and Dahlgaard, (1991) and van Donk and Sanders (1993) underpin the theory that organisational culture has an impact on quality management. They argue that cultural values are a frame of reference for daily practices and behaviour, and also for passing judgement on persons, actions and objects. Thus, culture dictates what people do, and what they see as either a good or bad quality. Therefore, culture may be regarded as a control mechanism for daily routines and the daily execution of operational tasks and must not be overlooked during the management of quality. Approximately two decades later, Malhi (2013) came to the same conclusion. He found that culture enables an organisation to self-regulate and it is significantly correlated with employee attitude and behaviour. He suggests that ultimately people are the creators of quality products and services since they make poor systems work and good systems fail, concluding that quality is the expression of human excellence.

Several other scholars (Evans and Lindsay 2017; Gambi, Jørgensen, Boer, Carpinetti and Gerolamo 2013; Knapp 2010; Jancikova and Brycha 2009 and McNabb and Sepic 1995) also studied the effect of culture on performance excellence in an organisation, in addition to the relationship between quality management and culture. These authors argued that a relationship exists between quality management, performance excellence and culture. Jancikova and Brycha (2009), in particular, argue that it is important for an organisation to be aware of their culture during quality management because organisational culture is an intangible key element that facilitates the adoption of quality management strategies and thereby differentiates an organisation from its competitors. Similarly, Evans and Lindsay (2017) advance that with regard to quality management toward performance excellence, an organisation must rely on its culture for optimal organisational success. This implies that quality management and performance excellence are dependent variables of the independent variable, culture.

2.2 The concept of Quality Culture

Organisational culture is defined as a set of shared values and assumptions maintained in a group (Evans and Lindsay 2017; Ahmed 2017; Mahli 2013; Gimenez-Espin, Jiménez-Jiménez and Martínez-Costa 2012; Cameron and Sine 1999). From this point of departure, Quality Culture can be seen as constituting a subsidiary component of organisational culture since Roldán, Leal-Rodríguez and Leal (2012) posit that an organisation's Quality Culture refers to its values about and interpretations of quality, as well as the manner in which it seeks quality. Citing Cameron and Sine (1999), they offer that:

"…*the quality culture of an organisation is a subset of an organisation's overall culture. It reflects the general approach, the values, and the orientation towards quality that permeate organisational actions*".

A robust association between Quality Culture and OpEx is highlighted by Evans and Lindsay (2017) who are of the view that successful OpEx strategy fits within an organisation's existing culture and capabilities, affiliated to the management of quality. Success is only achieved when every employee embraces an organisation's quality vision, values and goals as a way of life. Such an organisation is regarded as possessing a Quality Culture. Similarly, Evans and Lindsay (2017) emphasise the strong positive relationship between quality management, performance excellence and Quality Culture. Essentially, the presence of a culture of quality leads to OpEx. Quality Culture is a shared vision, and ultimately culture has a powerful influence on people's behaviour (Lindsay and Evans 2017).

The view of Lindsay and Evans (2017) was compared to that of Roldán, Leal-Rodríguez and Leal (2012), Jancikova and Brycha (2009), Jabnoun and Khalefa (2005), Pun (2001), Kanji and Yui (1997), Zeitz, Johannesson and Ritchie (1997), McNabb and Sepic (1995), Westbrook (1993) and Hildebrandt *et al.* (1991) who also propose various indicators of Quality Culture. Table 2.1 below presents a summarised outline of this comparison.

Table 2.1 General themes related to indicators of quality (Developed by the Researcher)

	Definition of Quality Culture in study and/or brief description on findings or recommendations of the study	**Indicators of Quality Culture**	**General theme:**
Evans and Lindsay (2017)	Quality Culture is described as a culture where every employee in an organisation understands how quality is defined in that organisation and embraces the organisation's quality vision, values and goals. Culture is reflected by management policies and actions. Quality Culture impacts performance excellence.	Organisation-wide common quality vision Top-down engagement Quality based performance expectations	Systems Approach Leadership Strategic Planning
Roldán, Leal-Rodríguez and Leal (2012)	Quality Culture is the 'values about', shared 'interpretations of', and the 'ways' an organisation seeks quality. They advance the use of quality techniques in an organisation is an indicator of Quality Culture.	Receptiveness to change/s (continuous improvement and innovation) Employee involvement Leadership commitment Learning opportunities	Agility Continuous Improvement Employee Empowerment Leadership Training
Jancikova and Brycha (2009)	Quality Culture is described as an adaptive culture that can satisfy the changing demands of customers, employees and	Continuous improvement External customer satisfaction	Continuous Improvement Customer Focus

	stakeholders, thereby enabling organisations to outperform others without such a culture.	Internal customer satisfaction Prevention Process Measurement Leadership Teamwork	Fact-based Management Leadership Employee Empowerment Agility
Jabnoun and Khalefa (2005)	Authors assert that effective quality management depends on an organisation's culture. They suggest that even without a dedicated quality management strategy, a culture of quality alone is sufficient to secure OpEx.	External customer satisfaction Organisational Quality Management Practices Training Benchmarking Supplier partnerships	Customer Focus Systems Approach Training Fact-based Management Supplier Management
Pun (2001)	Quality Culture is a prerequisite for an effective organisation. This shared set of values based on quality philosophy enables an organisation to adapt when needed and is characterised by organisation-wide learning opportunities and continuous improvement.	Work group/team quality activities Contact with customers Self-inspection and/or assessment Work simplification and/or redesign Cost of quality monitoring Close collaboration with suppliers	Training and Agility Employee Empowerment Customer Focus Fact-based Management Supplier Management Continuous Improvement

		Just-in-time practices	
Kanji and Yui (1997)	Quality Culture is constantly evolving in an organisation and customer delight is a key focus. It stimulates organisational progress through leaders in the organisation and drives business excellence.	Leadership Continuous improvement People make quality (teamwork) External customer satisfaction Internal customer satisfaction Work in progress Measurement and prevention	Leadership Agility Continuous Improvement Employee Empowerment Training Customer Focus Fact-based Management
Zeitz, Johannesson and Ritchie (1997)	Quality Culture supports and accompanies the implementation of quality management initiatives in an organisation. These authors propose that there are ten different features of Quality Culture that may be measured.	Good communication between management and employees Employee involvement and empowerment Trust between management and employees Innovation and continuous improvement Teamwork and conflict resolution Incentives	Employee Empowerment Leadership Continuous Improvement Strategic Planning Fact-based Management

		Employee commitment Clarity of role expectation Job challenge	
McNabb and Sepic (1995)	Quality Culture is the set of baseline values held on quality management in an organisation. Quality Climate is a related concept that influences Quality Culture and it must also be considered by an organisation when managing quality.	Basic organisational structure Role clarity Social support Technology	Systems Approach Leadership Employee Empowerment Training
van Donk and Sanders (1993)	The characteristics of an organisation's Quality Culture must be known for that organisation to develop and implement their quality management policies and procedures. Quality Culture should also be periodically reassessed in an organisation to determine if any changes have occurred in the baseline set of values.	Process or results orientation Employee or task orientation Parochial or professional orientation Open or closed system Loose or tight control Pragmatic or normative orientation	Strategic Planning Employee Empowerment Leadership Systems Approach Fact-based Management
Hildebrandt *et al.* (1991)	Quality climate is highlighted as an important conceptual element that is part of Quality Culture, in addition to shared	Leadership Internal customer satisfaction	Leadership Customer focus

	values, leadership and behavioural norms and a cultural network. These elements of Quality Culture manifest in relevant quality management constructs that can be measured	External customer satisfaction Employee involvement and motivation Training Participative and disciplined problem-solving and decision making Systems approach	Employee Empowerment Fact-based Management Systems Approach

Evident from Table 2.1 are common themes which emerge from listing the most frequent indicators of Quality Culture and into which indicators of Quality Culture can be categorised, namely, Leadership, Strategy, Systems Approach, Customer Focus, Continual Improvement, Employee Empowerment, Fact-based Management, Supplier partnership, Training and Agility. Research shows that these themes may be considered as constructs of the data collection instrument that is to be designed by this study, to examine Quality Culture. Another commonality noted was that all authors stated or implied that Quality Culture in an organisation is an independent variable that affects quality management strategies which have an impact on OpEx in an organisation.

Notwithstanding the preceding, the views of Evans (2017), Mosher, Keren and Hurburgh (2013), McNabb and Sepic (1995) and Hildebrant *et al.* (1991) are significant to this research study. These authors advocate that the examination of climate during quality management should take place in conjunction with the examination of Quality Culture. Although not explicitly stated by all, the findings of the research conducted by all these authors imply that quality climate is an influential component of a culture of quality. Therefore, this literature review progresses with examining indicators of quality climate.

2.3 The concept of Quality Climate

Mosher, Keren and Hurburgh (2013) examined Quality Culture as a concept. They defined Quality Climate as the shared perceptions employees have relative to the importance of policies, procedures, and practices. Thus Quality Climate refers to perceptions that influence behaviour and resides within Quality Culture. They opined that Quality Climate has largely been ignored by researchers despite that Quality Climate impacts employee behaviour, employee participation, commitment and training. These are considered to be substantial predictors of improved organisational quality. Consistent with this, Evans (2017) posited that some writers use 'culture' and 'climate' interchangeably. These two concepts are not the same, despite being closely related. He describes quality climate as the attitudes, hopes and biases of people in an organisation during the management of quality. Both these authors suggest that, while climate is a significant influential factor that impacts culture, it must still be measured independently. The inference drawn from the above is that a comprehensive and holistic study of Quality Culture must include an examination of the Quality Climate.

McNabb and Sepic (1995) report that, within the context of quality management, the climate of an organisation emerges from the interaction of people and its underlying culture. Culture sets the boundaries of behaviour in the group. They describe quality climate as the 'atmosphere' that is present during the management of quality in an organisation. Climate is thus a reflection of culture that is displayed by the qualities and abilities of people in a particular group. It is

altered more readily than culture; however, it is as enduring and pervasive in the group. Climate influences the behaviour within the group and with parties external to the group. Thus, it influences the content and the strength of prevalent values, norms, attitudes, behaviours and feelings of the people in the group. Importantly, they note that it represents a form of organisational support. In particular, climate represents the degree of openness within the group, the degree of autonomy and quality of relationships within the group and conflicts within the group.

Dastmalchian, Blyton and Adamson (1991) argue that culture is a product of climate. Several scholars (Jacobs 2015; Weeks, Roberts, Chonko and Jones 2004; McNabb and Sepic 1995) have since contested this belief, arguing that, although culture is related to climate, culture does not stem from the climate. These authors assert that climate and culture form a feedback loop. McNabb and Sepic (1995) suggest that the shared values that constitute culture feed characteristics of climate. These measurable indicators of climate include 'overall environment', 'communication', 'conflicts' and 'leadership'. Indicators of culture, together with organisational policies have an impact on culture, as seen in an adaptation of the Model proposed by McNabb and Sepic (1995) in Figure 2.1.

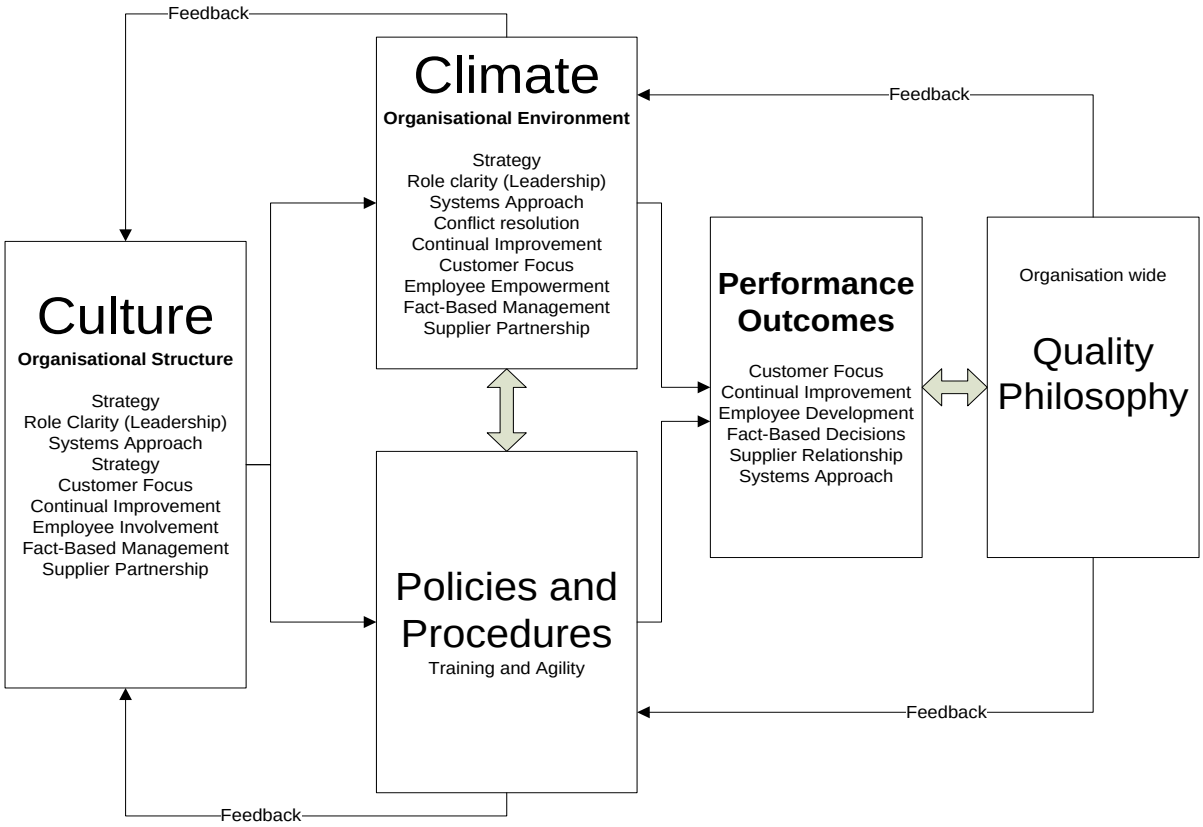


Figure 2.1 Relationship between Culture, Climate, Policies and Procedure and Performance Outcomes leading to Organisational Quality Philosophy (adaptation of McNabb and Sepic 1995)

The examination of the concepts of Quality Culture and quality climate is interrogated because it guides this study to recognise the importance of both Quality Culture and Quality Climate and thus helps to identify indicators of Quality Culture and the indicators of climate during quality management. Cognisance will be taken of both types of indicators during the development of a research instrument in Chapter Four and the analysis of data in Chapter Five.

2.4 Competing values of Quality Culture

The preceding discussion identifies indicators that may be used to measure culture and climate in the context of quality management. The underlying premise proposed by the authors above is that these indicators reflect different quality management constructs or measurable constructs of culture and climate in an organisation. Numerous studies (Lapiņa, Kairiša and Aramina 2015; Gambi, Gerolamo and Carpinetti 2013; Gimenez-Espin, Jiménez-Jiménez and

Martínez-Costa 2012; Roldán, Leal-Rodríguez and Leal 2012; Knapp 2010; Jabnoun and Khalefa 2005; Prajogo and McDermott 2005) have, however, demonstrated that, in addition to measuring constructs of Quality Culture, it is advantageous to use the competing values framework to classify culture further and study its effect on quality management. This framework, originally proposed by Cameron and Quinn (1999) recommends the typification of culture on the basis of flexibility or rigidness and on the basis of outward or inward focus. This typification adds value to any study of culture, as it allows quality practitioners to view Quality Culture from a fresh perspective which enables vital decision-making pertaining to the adoption of business strategies, on the basis of an organisation's cultural characteristics.

An adaptation of an instrument, known as the Organisational Culture Assessment Instrument (OCAI), was used by each of the aforementioned studies in their research on quality management to identify organisational culture profiles. The OCAI measures competing values in an organisation within two different dimensions. Each dimension represents a continuum, with contrasting values (which reflect organisational aptitude) at opposite ends. The first dimension differentiates an organisation's focus in terms of flexibility and dynamism on the one end, from a focus on stability, order and control at the other end of the continuum. Knapp (2010), Prajogo and McDermott (2005) explain that some organizations are effective because they are changing, adaptable, and agile, and thus more flexible and dynamic. Conversely, other organisations are effective because they are stable, predictable, and mechanistic, thus more ordered and controlled. Thus, it is understood that certain organisations are effective because they are more flexible, while other organisations are effective because they are more stable.

The second dimension, as clarified by Knapp (2010) and Prajogo and McDermott (2005), differentiates organisations on the basis of internal or external orientation. An internally orientated organisation will have strong elements of internal harmonisation and integration while an externally orientated organisation is fiercely competitive and engaged in rivalry with others outside their borders. When the two dimensions are united, they form four quadrants. Each quadrant

represents a distinct organisational cultural type, with a distinct set of characteristics, as seen in Figure 2.2.

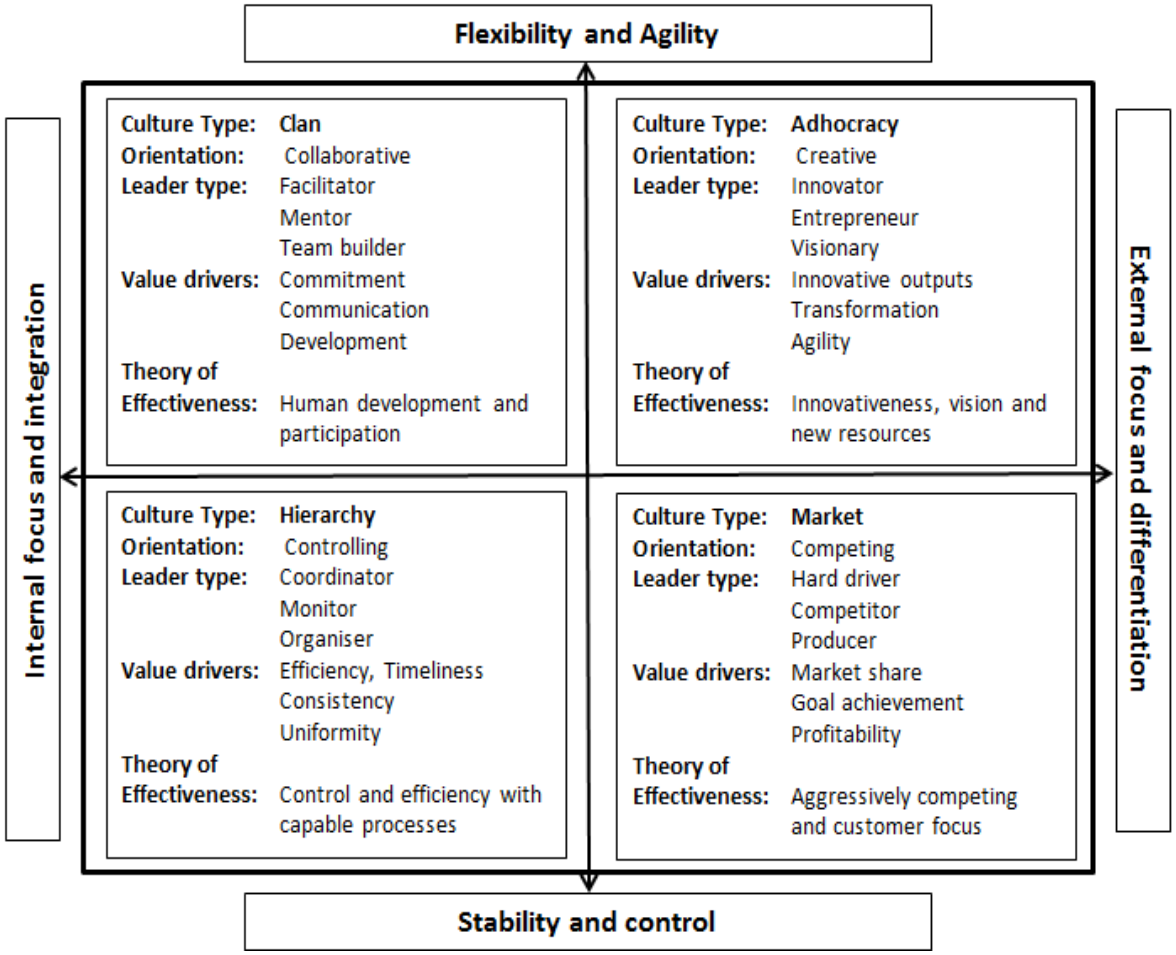


Figure 2.2 Competing values framework (Adapted from Cameron and Quinn 1999)

Each of the four quadrants represents how people in a particular organisation operate; and the behaviour that is considered appropriate and valued in that organisation. Expanding on Prajogo and McDermott's (2005) view, Gimenez-Espin, Jiménez-Jiménez and Martínez-Costa (2012) position the four culture types on the two-dimensional axis. On the flexibility-rigidness axis, they state that group culture is positioned on the flexible end as it emphasises the internal adaptability of the organisation. Teamwork, participation, empowerment and concern for ideas are key characteristics of group culture. They refer to group culture as 'clan culture'. The developmental culture also resides on the flexible end of the flexibility-rigidness axis; however, the additional focus of this culture type is external to the organisation. Growth, innovation, creativity and continual

adaption to the external environment are valued in this culture type. The developmental culture is referred to as the ‘adhocracy culture’.

The rational culture exists on the rigid end of the flexibility-rigidness axis, and like the adhocracy culture is also focused on the external environment. The rational culture is, however, more control-orientated as opposed to flexible, as the former two culture types are. This culture places emphasis on competition, goal achievement, performance and productivity. Task focus and clarity, efficiency and high performance characterise this culture type. The rational culture is also referred to as the ‘market culture’. The final culture type, namely hierarchical culture, is also control-orientated, and therefore, positioned on the rigid end of the flexibility-rigidness axis. This culture type has a more inward internal focus when compared to the rational culture. Stability, centralisation and predictable outcomes are valued in this culture.

Cameron and Quinn (2011) and Knapp (2010) propose that, although it would appear as if the cultural types located in opposite quadrants are contradictory, they are not mutually exclusive. The authors hold that, because organisations exist in dynamic environments, one organisation can simultaneously exhibit competing values. In essence, the authors argue that different components of the various cultural types work in an interrelated way to establish balance and effectiveness. Most organisations tend to have one dominant cultural profile. However, the prevailing environmental factors that an organisation is faced with could result in an organisation exhibiting traits from all four quadrants at any given time (Cameron and Quinn 2011; Knapp 2010).

From this literature review, it can be concluded that the competing values framework is a suitable instrument to identify the dominant cultural traits of pharmaceutical manufacturers in South Africa. These cultural traits can be compared to the results of the relationships between Quality Management Practices, Quality Culture and Climate in those organisations, to generate a holistic view of the prevailing landscape of the South African pharmaceutical industry. It is believed that such an examination is capable of highlighting the cultural characteristics needed to support Quality Management Practices and

thereby enable this study to develop a conceptual Model of best practices for Category A manufacturers in South Africa.

2.5 Performance frameworks for Quality Management

The literature presented in section 2.2, 2.3 and 2.4 identify indicators that can be used as statistical constructs to measure culture in the context of quality management. This study now sets out to characterise a practical Model into which the aforementioned indicators can be positioned. The focus of this literature study will lean toward the scrutiny of international quality awards in the following section, to provide a framework for the development of a conceptual OpEx Model by this study.

There is general consensus (Ladzani 2016; Business Excellence Tools 2016; Smit, Cronje, Brevis and Vrba 2011; Williams 2008; Stading and Vokurka 2003; Adebanjo 2001) that OpEx in an organisation is attainable through the implementation of a Model of practices which is designed from a framework of criteria rendered by an internationally recognised quality awards programme. Quality awards programmes not only promote quality awareness through the recognition of quality initiatives and achievements of organisations but also facilitate OpEx in an organisation. Williams (2008) claims that quality award frameworks have historically formed a foundation for the development of numerous well known Business Excellence Models since they contain a set of quality criteria that address all the areas that are critical to sustainable quality improvement and OpEx within an organisation's operations.

Ladzani (2016) argues that a Model of Quality Management Practices helps an organisation to focus thought and action in a systematic and structured way which should lead to increased performance. A Model is easy to understand and provides an organisation with straightforward guidance on strategies to ensure compliance with a standard and improve on quality management. Stading and Vokurka (2003) believe that quality award criteria serve as reference points that indicate which organisational processes should be improved and which should be monitored, thereby giving an organisation a competitive edge. The utilisation

of a Model based on awards criteria manifests as strategy since it ensures adaptation of quality management systems based on requirements resulting in market differentiation, competitive advantage and success. A similar view is expressed by Adebanjo (2001) who states that the adoption of a Model presents opportunities for self-assessment and benchmarking. It is a tool to assist organisations to evaluate their current levels of performance, identify and prioritise areas for improvement, integrate improvement actions into business plans and identify best practice.

Furthermore, when follow-up assessments against the same award criteria are performed, progress towards excellence can be measured, and this promotes continuous improvement. Thus, a Model is a tool to direct strategic planning (Ladzani 2016; Smit 1999). From this, it can be inferred that a Model developed for the pharmaceutical industry in South Africa will assist organisations to meet the requirements of GMP and simultaneously secure OpEx.

Ladzani (2016), Williams (2008), Stading and Vokurka (2003) and Smit (1999) believe that the most commonly known quality awards that have been used to develop business excellence Models are the Japanese Quality Award, known as the Deming Prize (DP), the United States Quality Award, known as the Malcolm Baldridge National Quality Award (MBNQA) and the European Quality Award, known as the European Foundation for Quality Management Award (EFQMA). These awards, their award criteria, their contribution to quality management and significance to this research will be discussed in the following sections.

2.5.1 The Deming Prize

The DP was established in 1951 by the Union of Japanese Scientists and Engineers. It is recognised as the world's first business excellence award. There are three award categories in the DP namely: a DP for individuals, a QC award for factories (restricted to Japanese applicants only) and a DP for organisations (open to non-Japanese organisations and Japanese organisations) (Smit 1999). Williams (2008) explains that the DP evaluates applicants on the basis of organisation-wide quality control. The DP award process involves the evaluation

of an organisation against ten equally weighted categories, specifically: policies; organisation; information; standardisation; human resources; quality assurance; maintenance; improvement; effects and future plans. These categories are considered to be the quality award criteria.

A noteworthy and distinguishing characteristic of the DP, highlighted by Ladzani (2016), Williams (2008) and Stading and Vokurka (2003) is that the DP award criteria are not formally depicted in an illustration (of the Model) by the bestowers of the award, as other quality awards are. Porter and Tanner (2004), however, present a framework of the award criteria in the form of a diagrammatic representation of the DP, which is comparable to a Model and can be seen in Figure 2.3.

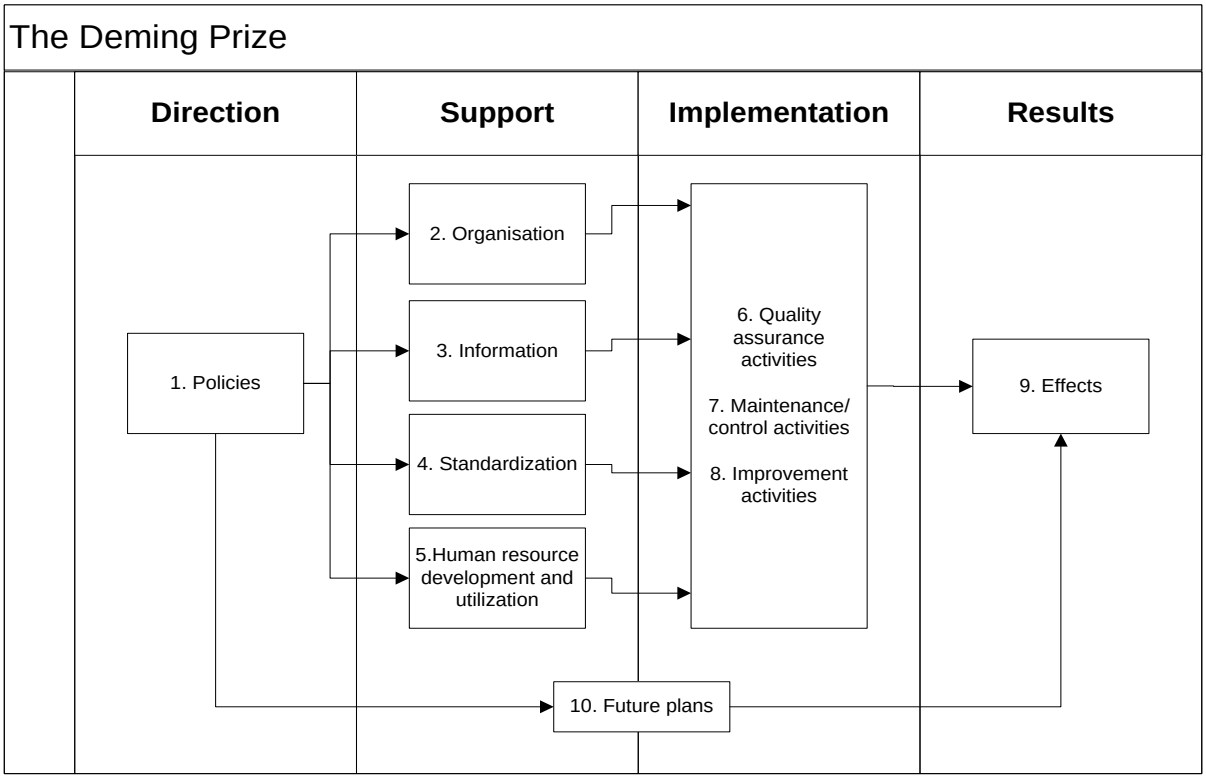


Figure 2.3 The Deming Prize Framework (Porter and Tanner 2004)

The focus of the DP is on self-assessment. The strength of using the DP award criteria in an endeavour towards OpEx lies in its emphasis on management commitment, strategic planning, process control, tenable Kaizen improvement opportunities and future planning that ensure improvement gains are sustained. Williams (2008) reports that a major shortcoming with the adoption of the DP

criteria as an organisational strategy is that the DP award criteria are highly prescriptive in nature. She implies a strict audit-like approach is followed during the evaluation of an organisation for the DP since specific tools, techniques and practices to be used are stipulated by this award criteria, for instance, statistical process control (SPC), quality circles, standardisation, among others. In consideration of the aforementioned, it can be gleaned that appropriate award criteria can serve as a self-assessment tool when it is used in a Quality Management strategy or a conceptual OpEx Model. Importantly, however, it is noted that the criteria should offer guidance, as opposed to prescribing very specific quality tools and techniques, for it to be adopted in an organisational OpEx strategy.

2.5.2 The Malcolm Baldrige National Quality Award

Williams (2008) describes the MBNQA as the best-known quality award and the most widely used quality self-assessment tool employed by organisations. It was established in the United States in 1987 when then-President Ronald Reagan signed the Malcolm Baldrige Quality Improvement Act to encourage organisations to adopt Quality Management Practices in order to gain a competitive advantage over other organisations. The MBNQA is non-prescriptive since it does not require any particular methods or tools to be used to improve quality.

Discussing Baldrige award criteria, Westcott (2006) asserts that performance in an organisation is measured based on targets in seven areas namely, leadership perspective; strategy perspective; customer perspective; process measurement, analysis and knowledge management perspective; employee perspective; operations perspective and financial perspective. Stading and Vokurka (2003) refer to the leadership perspective; strategy perspective and customer perspective as the ‘leadership triad’ and the employee perspective; operations perspective and financial perspective as the ‘results triad’. The process measurement, analysis and knowledge management perspective supports both the leadership triad and the results triad as seen in Figure 2.4.

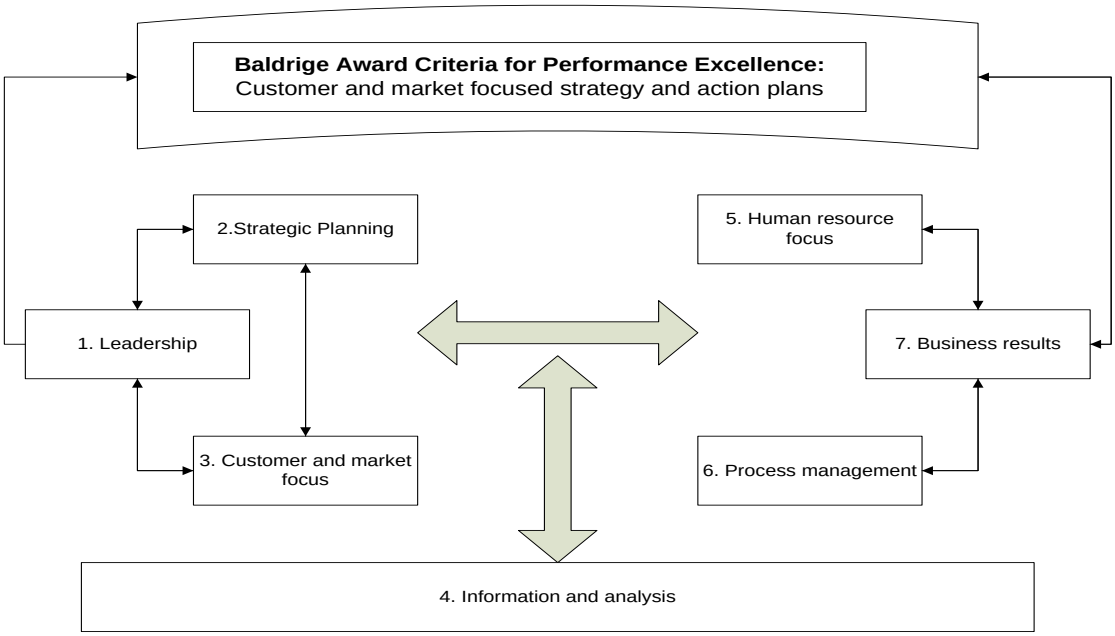


Figure 2.4 Baldrige award criteria for performance excellence (Stading and Vokurka 2003)

The seven awards criteria allow organisations to track their progress to targets while simultaneously evaluating the strategy being used, to determine if it is adequate to meet targets in the areas mentioned above. In addition to this, it also facilitates the identification of opportunities for improvement (OFIs) in organisations and in so doing improves their strategy should they adjust accordingly. Williams (2008) proposes a framework for the MBNQA that consists of four basic elements that allow easy comparison with the DP. These elements are the driver, the system, measures of progress and goal. A diagrammatic representation is presented in Figure 2.5.

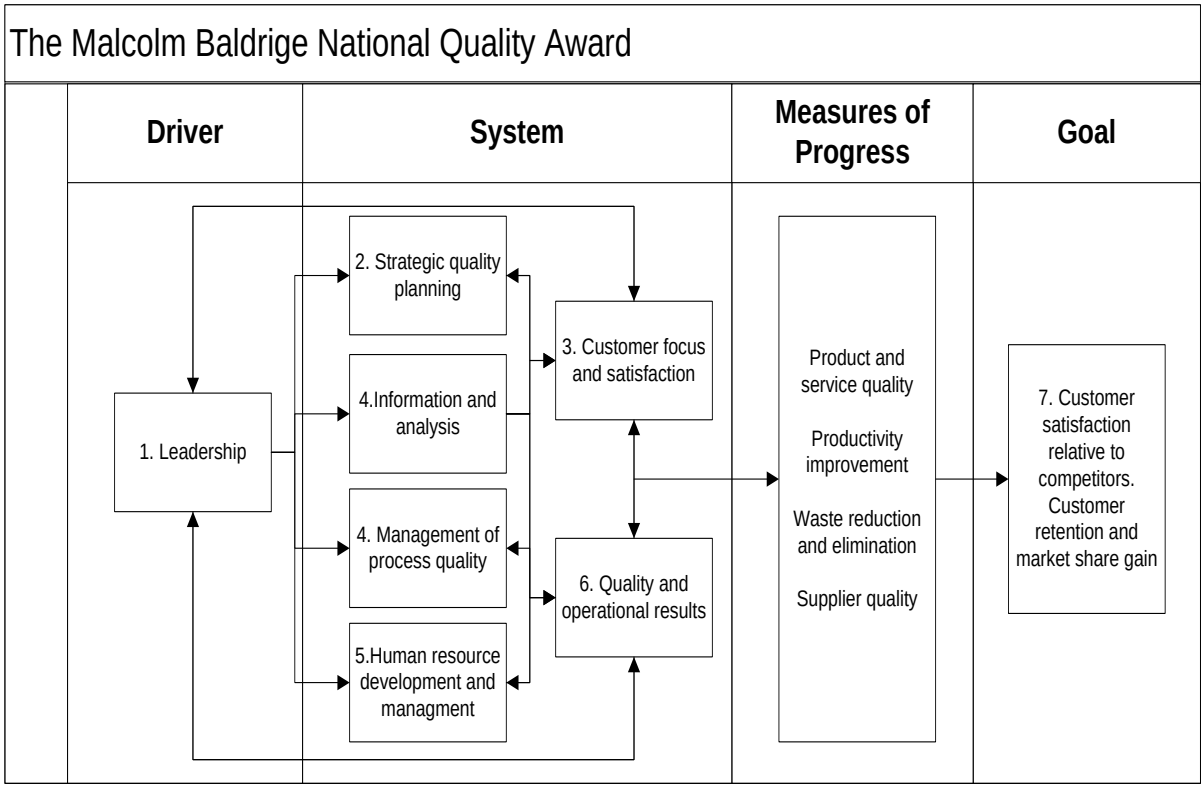


Figure 2.5 The Malcolm Baldrige National Quality Award Framework (adapted from Williams 2008)

Williams (2008) clarifies that the focus of the MBNQA is on results. Being more results-oriented than the DP, the MBNQA does not prescribe a particular method or set of tools to achieve results - rather the MBNQA supports a systematic approach to maintaining goal alignment throughout the organisation. Collectively, the intention of the award criteria is to assist an organisation to adopt an approach aligned to organisational performance management while maintaining customer focus in all organisational operations and activities. Ladzani (2016) believes that there are certain disadvantages to using the MBNQA award criteria to secure OpEx. These are time-consuming adoption, organisational fear of assessment findings which serves as a barrier to implementation, no perceived need for the MBNQA and a lack of trained examiners to do assessments. The preceding literature highlights the usefulness of adopting a results-focus for quality award criteria. This foregrounds the importance of having targets during an organisational endeavour towards excellence in operations.

2.5.3 The European Foundation for Quality Management Award

Ladzani (2016) states that 14 major West European countries formed the European Foundation for Quality Management (EFQM) in 1988. In 1991 the EFQM launched the EFQMA to honour outstanding European businesses. According to Williams (2008), two different prizes are awarded by the EFQM. These are an award for an organisation that demonstrates OpEx due to the management of quality and continuous improvement in that organisation, and a separate award for the organisation regarded to be the most successful exponent for the principles of quality management in Western Europe.

Scholars (Ladzani 2016; Jancikova and Brychta 2009; Williams 2008; Stading and Vokurka 2003) report that the EFQMA measures performance in nine different areas. Five of these measurement areas are referred to as enabler criteria. Enabler criteria are 'leadership', 'strategy' 'partnerships and resources', 'employees and processes' and 'services and products'. The remaining four measurement areas are referred to as results criteria. The results criteria are 'customer, 'employee' 'society' and 'business results'. A diagrammatic representation of the EFQMA is presented in Figure 2.6.

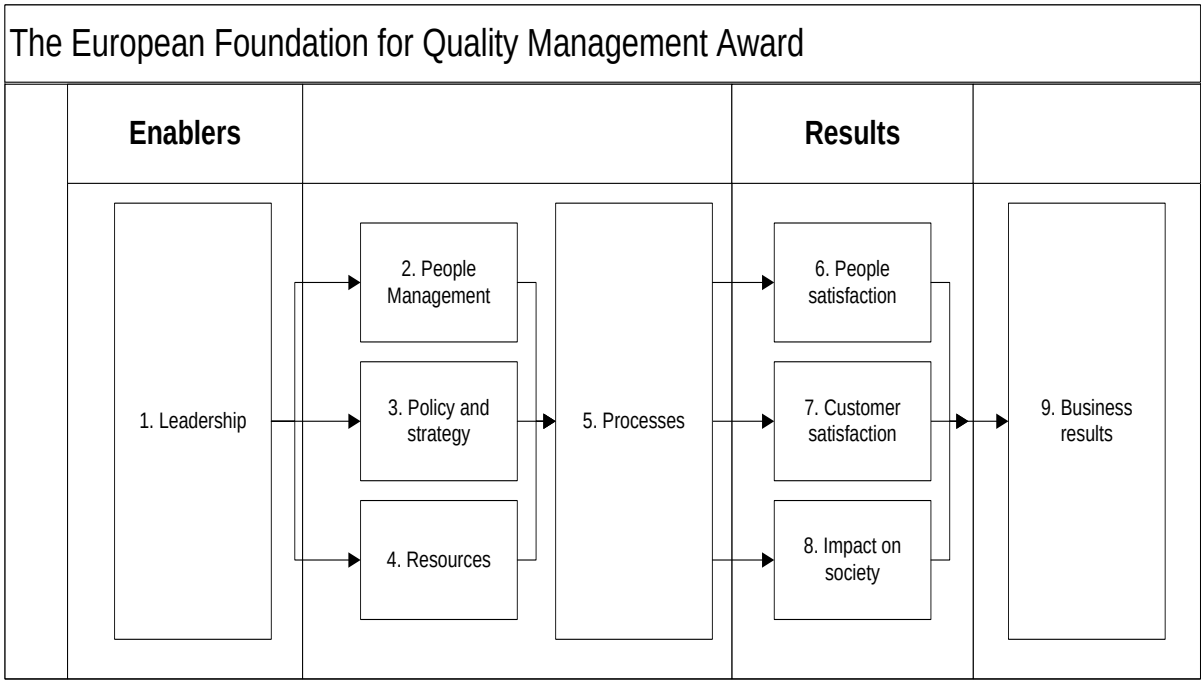


Figure 2.6 The European Foundation for Quality Management Award Framework (adapted from Ladzani 2016)

Jancikova and Brychta (2009) affirm that using the EFQMA award criteria to gauge an organisation's quality management is an effective tool to measure an organisation's competitive advantage during benchmarking and also serves as the basis for continuous improvement in that organisation. The award criteria are also regularly reviewed and updated by the EFQM based on feedback from industry consultants. Ladzani (2016) cautions, however, that there are some concerns associated with the use of EFQMA criteria to achieve OpEx. He mentions that organisations questioned the merit of measuring themselves against criteria with an associated score rating when the number of points scored in a specific area is no guarantee of the accuracy of the number of internal or external defects recorded in an organisation, or the vehemence of customer complaints. In addition, after initial gains, management of organisations stopped seeing the value of using EFQM criteria beyond approximately the third cycle of assessment. They started using the criteria to assess unit managers, rather than focus on the improvement of business performance (Ladzani 2016).

In spite of criticisms levelled against EFQMA criteria, Researchers (Ladzani 2016; Jancikova and Brychta 2009; Williams 2008; Stading and Vokurka 2003) agree that the relevance and importance of this Model (award criteria) cannot be disputed. It is a tool to direct strategic planning. Based on sound quality principles, it serves as major impetus for organisations striving for performance excellence and the competitive edge. Furthermore, a notable feature foregrounded by the aforementioned literature on the EFQMA is that award criteria can also serve as the basis for continuous improvement when it is regularly reviewed and updated. Quality award criteria are, therefore, aligned with the endeavour to achieve excellence in operations in an organisation.

2.5.4 Synopsis of the evaluation of Quality Award Criteria

Evaluation of the three most commonly known quality award criteria enables this study to deduce that, although award criteria of different international quality awards are not identical, there are some criteria that are common. There are also overlapping focus areas of award criteria that are deemed important. Significantly, rapport was noted between quality award criteria and the indicators of Quality Culture, as seen in Table 2.2. It can be deduced from Table 2.2 that

indicators of Quality Culture may be used to measure elements of a quality strategy, in the same way, quality management award criteria evaluate quality management in an organisation. Thus it is presumed that a Model of Quality Management Practices that will assist South African pharmaceutical organisations to become operationally excellent may be developed within the boundaries provided by the indicators of Quality Culture.

Table 2.2 Comparative summary table of Quality Award Criteria (Developed by the Researcher)

Deming Prize	**Malcolm Baldrige National Quality Award**	**European Foundation for Quality Management Award**	**Indicators of Quality Culture (and climate as a subset of Quality Culture)**
	Leadership	Leadership	Leadership
Policies		Policy and strategy	Strategy
Information	Information and analysis		Fact-based management
Organisation (system)			Systems approach
		Resources	Systems approach
Maintenance and control activities	Management of process quality	Processes	Training and agility
Standardisation			Systems approach
Human resource development and utilisation	Human resource development and management	People management and people satisfaction	Employee empowerment
	Customer focus and satisfaction	Customer satisfaction	Customer focus
	Measure of progress: Supplier partnership		Supplier partnership
	Measure of progress: Waste reduction and elimination		Continual improvement

Deming Prize	Malcolm Baldrige National Quality Award	European Foundation for Quality Management Award	Indicators of Quality Culture (and climate as a subset of Quality Culture)
Improvement activities	Measure of progress: Product and service quality; Productivity improvement.		Continual improvement
Quality assurance activities			Customer focus; Training and agility
		Impact on society	
Effects (Results)	Quality and operational results	Business results	
Future planning	Strategic quality planning		Strategy

In considering the commentary in the foregoing section and emulating a function of quality awards, a conceptual OpEx Model designed for South African pharmaceutical manufacturing organisations is believed to be capable of serving as a self-assessment tool in an organisation's endeavour towards OpEx. Since compliance with GMP is non-negotiable (Friedli and Bellm 2013b, Lengal 2009 and Coffey 2008) in the pharmaceutical industry, the design of the Model should both facilitate GMP compliance and excellence in operations. It can be gleaned that a GMP based strategy supported by an organisational mindset founded in Quality Culture constitutes the best way to realise OpEx.

2.6 Chapter summary

This chapter established a theoretical link between the concept of Quality Culture and Quality Climate with the success of quality management in an organisation. Following this, an evaluation of the three most widely known international quality awards provided this study with a theoretical platform for the analysis of data which will be undertaken in Chapter Six Quantitative Study Results and Discussion, and development of the conceptual OpEx Model which takes place

in Chapter Seven Model Development. An unexplored variable highlighted by the synopsis of three award criteria is GMP. Therefore, the next chapter progresses with an examination of this important regulatory standard in the pharmaceutical industry.

CHAPTER THREE
GOOD MANUFACTURING PRACTICE

'Experience by itself teaches nothing... Without theory, experience has no meaning. Without theory, one has no questions to ask. Hence, without theory, there is no learning.'

- Dr William Edward Deming

Since the advent of formalised quality management in the latter half of the twentieth century, numerous Models aimed at achieving performance excellence have been proposed in various industries across the globe (Evans 2017). A striking and nuanced characteristic of a Model designed for the pharmaceutical industry, however, is that it must comply with GMP, which is absent at present. Thus this chapter establishes, in three sections, theoretical associations between GMP and Quality Management Practices within the context of the heavily regulated pharmaceutical industry. Section one of this chapter presents the global factors that necessitated and shaped current regulation. Section two of this chapter is a discussion on Quality Management Practices employed to assist pharmaceutical organisations in complying with regulations, both from a global perspective as well as a South African perspective. Finally, section three highlights some of the most common quality strategies that may be used by pharmaceutical organisations to improve operational performance. This chapter, therefore, addresses the first two objectives of this research study which are to identify the most common Quality Management Practices to support business performance and regulatory requirements in the pharmaceutical industry and to conduct an explorative literature study on OpEx strategies used in the global pharmaceutical industry.

3.1 The rise of global regulatory factors in the pharmaceutical industry

Patel and Chotai (2008), define GMP as a globally important set of regulatory clauses that serve as a guideline for the manufacture of pharmaceutical substances, pharmaceutical products, medical devices and food. Good Manufacturing Practices garnered international prominence due to a global realisation that unaccompanied final product testing is not sufficient to ensure the

manufacture of good quality products that are entirely safe to use within pharmaceutical production. Woodcock (2012) uses the term "*devastating*" to describe the most severe consequences of quality problems in the global pharmaceutical industry, specifically the large-scale number of fatalities and illnesses that have been caused by poor quality pharmaceutical products. These severe negative consequences triggered the global movement, where official regulatory guidelines and statements on GMP for medicinal products were defined in countries across the world.

3.1.1 Tragic events that led to the promulgation of Good Manufacturing Practice

DeRoo (2014) and Patel and Chotai (2008) report that GMP is regarded as the global response to the tragic occurrences that evoked mechanisms to prevent future tragedies. They state that the most significant contributing factors for the initiation of GMP in the pharmaceutical industry were as follows: the 1901 Diphtheria Tragedy, the 1937 Wonder Drug Tragedy, the 1941 Sulfathiazole Disaster, the 1955 Polio Incident and the 1962 Thalidomide Tragedy. Consequently, these tragedies played a formative role in the development and design of GMP, hence all clauses in GMP were reactively drafted to ensure that events that led to these tragedies would not recur. Each of these tragedies and their contribution to the development of regulations is highlighted in the discussions below to illustrate the importance of compliance to GMP in the pharmaceutical industry. Furthermore, the elucidation of GMP will provide this study with insight into the legislative requirements which must be considered during model development in Chapter Seven.

3.1.1a The 1901 Diphtheria Tragedy

Prior to 1902, there was no global legislation for the manufacture of pharmaceutical products. A legislative position was initiated in 1901 when children who received treatment for diphtheria died of tetanus because the horse serum that had been used to prepare the antitoxin treatment was contaminated with tetanus. An order to destroy the serum was issued but was never carried

out. As a result of this incident, 13 children died (DeHovitz 2013; Patel and Chotai 2008).

The outcome of this tragedy resulted in recognition of the need for regulatory safeguards during the pharmaceutical manufacturing process. DeHovitz (2013) states that the United States government passed the Biologics Control Act in 1902, which gave the government overarching control over the manufacturing processes used to make biological products and the responsibility to ensure their safety for the American public. Patel and Chotai (2008) outline that, while this Act was passed in the United States, it had global influence and began a change in the mind-set in many countries across the world, as it was realised that governmental regulation was needed to protect the users of medicinal products.

In alignment with this, a follow-up Act was passed in 1906, namely the Pure Food and Drug Act. Patel and Chotai (2008) suggest that the implication of the introduction of an additional legislative requirement was that it became mandatory that all potentially harmful ingredients in food and medicinal products be labelled. Any omission of labelling or inaccurate labelling became a punishable offence. When GMP was drafted between 1962 and 1966, this requirement was included in the guideline to ensure the safety of product users.

3.1.1b The 1937 Wonder Drug Tragedy

Akst (2013) and Patel and Chotai (2008) recount the incident of 34 children and 73 adults who died after consuming a 'wonder drug' called Elixir of Sulfanilamide in 1937. This pharmaceutical product was touted as a treatment for a variety of ailments ranging from gonorrhoea to a sore throat. The solution contained 10 per cent sulphanilamide, 72 per cent diethylene glycol solvent and 16 per cent water. The solvent was later discovered to be the cause of the deaths. Akst (2013) reports that, under the regulations of the time, the pharmaceutical manufacturer had not breached any legislation, as laboratory tests revealed that the ingredients claimed to be in the pharmaceutical product were exactly as the Organisation had stated. The Organisation did not, however, test the safety of the product before it was released to the market.

This incident highlighted the importance of verifying medicinal product safety before marketing them. The United States Food and Drug Administration (FDA) was launched in 1906, to regulate the industry. However, until 1937, the primary function of the FDA had been to merely police claims manufacturers made about ingredients in food and pharmaceutical products. Akst (2013) and Patel and Chotai (2008) report that no formal government approval was needed to market new pharmaceutical products. The Wonder Drug Tragedy of 1937 brought to light the need for a formal quality control process to ensure the safety of all new medicinal products prior to their release to market.

This tragedy, drawing from the discussion above, provided the impetus for passing the 1938 United States Food, Drug and Cosmetics Act that mandates organisations to prove products are safe before being released to the market. The 1937 Wonder Drug Tragedy impacted on global pharmaceutical regulation by highlighting the importance of preclinical trials. An organisation must, to comply with GMP, include pre-clinical and clinical information in support of the efficacy and safety of the formulation, dosage form, dosage regimen and side-effects of a pharmaceutical product, before a licence to market the product is granted.

3.1.1c The 1941 Sulfathiazole Disaster

In 1941, nearly 300 people were killed or injured by sulfathiazole grains manufactured by Winthrop pharmaceutical organisation. The medication, namely Sulfathiazole, was tainted with the sedative phenobarbital (DeRoo 2014; Patel and Chotai 2008). Swann (1999) states that Winthrop had followed all the statutory prescriptions necessary at the time of manufacture. This included reporting the chemical composition of the pharmaceutical to the FDA. They also circulated the results of the successful pre-market clinical trials.

In March 1941 the FDA received a report of a three-year old girl who had slipped into a coma after consuming 15 grains of Sulfathiazole. This incident drew attention to the extent of the responsibility required of the pharmaceutical manufacturer. Two new factors emerged that had not previously been considered by the pharmaceutical industry. Firstly, ‘cross-contamination’ can

occur when different pharmaceutical products are manufactured in the same area. Secondly, an effective product 'recall plan' is needed when a defective product is reported to the manufacturer (Swann 1999).

According to Swann (1999), the FDA investigations disclosed that two tabletting machines used to manufacture Sulfathiazole were in the same room, adjacent to one other. These machines were used interchangeably to manufacture Luminal, another product. Luminal is an anti-epileptic pharmaceutical product constituted using phenobarbital. In small doses phenobarbital is used to treat epileptic seizures; however, it is also the most commonly used agent in high purity and in large enough dosage as a lethal injection for death row criminals. Swann (1999) asserts that an employee inadvertently swopped the active pharmaceutical ingredients used to make the products.

The second factor highlighted by this incident was the importance of an effective recall plan for products. Swann (1999) states that, although Winthrop became aware of cross-contamination in December 1940, it was only after the FDA's intervention in March 1941 that effectual attempts were made to recall the defective products from both primary and secondary distributors. He claims that, if Winthrop had effectively and adequately responded to reports of product contamination when they were received in December 1940, at least 64 deaths and 143 adverse drug reactions (ADRs) could have been averted.

Swann (1999) concedes that the incident did not have an immediate effect on the laws governing pharmaceutical production at the time. It only influenced the development of regulation governing pharmaceutical manufacturing practices approximately 27 years later in 1968, when GMP was mandated, and guidelines were drafted to ensure that proper cleaning and validation of manufacturing equipment took place between batches of different products being manufactured using the same equipment, to prevent cross-contamination.

In addition, the GMP guideline also specifies that an organisation must have a system in place to recall any product from the market or public consumers. Accordingly, the organisation must adequately address all complaints about

marketed products. The causes of quality defects should be investigated, and appropriate measures (corrective action and preventive action) should take place in respect of the defective products, to prevent re-occurrence (Swann 1999). From this incident, this study establishes that validation management, an effective recall process and a corrective action and preventative action (CAPA) process are critical practices required in the pharmaceutical industry.

3.1.1d The 1955 Polio Vaccine "Cutter Incident"

Offit (2006) states that, on the 12th of April 1955, five pharmaceutical organisations in the United States were granted regulatory approval to manufacture the polio vaccine. Cutter Laboratories was one of these five organisations. The manufacturing process of the vaccine involved the inactivation of a live polio virus with formaldehyde.

Two weeks after the release of the vaccine, reports surfaced of five children who became paralysed after being inoculated. In each case, the problematic vaccine was traced back to Cutter Laboratories. According to Offit (2006), among all the children who had received the vaccine, records indicate that 40 000 suffered from headaches, stiff necks, fever and muscle weakness, while 51 children were permanently paralysed and 5 children died. Furthermore, he claims that the vaccine started an epidemic, as 113 people in the affected children's families or communities were also paralysed and 5 more people died.

Offit (2006) adds that the cause of the problem was revealed when it was discovered that two production pools of vaccine manufactured by Cutter Laboratories contained live polio virus. He claims a lack of quality control during the manufacturing process led to an unsafe vaccine being distributed to the public. Consequently, ex post facto GMP guidelines were drafted in 1967 to include a clause on quality control. It can be deduced that the function of this clause is to ensure that effective quality control of products takes place, independent from any influence due to the production objectives or targets of the organisation. Accordingly, GMP stipulates that there should be a head of quality control in the manufacturing organisation which ensures quality control practices

are performed and that this should not be the same person as the head of production.

3.1.1e The 1962 Thalidomide Tragedy

The final and most significant event that influenced the structure of global pharmaceutical regulation is the Thalidomide tragedy. Thalidomide is a sedative that was originally sold in West Germany in 1956 (Rägo and Santoso 2008). It was marketed as a sleeping pill and as a treatment for morning sickness. Between 1958 and 1960, thalidomide was globally marketed in 46 countries. Patel and Chotai (2008) point out that, when the national pharmaceutical regulatory authorities (NRAs) in Europe granted permission to pharmaceutical organisations to market the product, they were unaware of the product's teratogenicity, which emerged later.

Rägo and Santoso (2008) and Patel and Chotai (2008) concur that an estimated 10 000 babies were born with birth deformities linked to the use of Thalidomide. This tragedy is arguably the event that prompted a united globalised effort to regulate medicines via the World Health Organisation (WHO). The Thalidomide incident galvanised public opinion and legislators punted for more stringent controls globally. This tragedy brought into sharp focus the importance of thorough, rigorous and relevant testing of pharmaceutical products for any side-effects prior to their introduction into the marketplace. Furthermore, this incident highlighted the importance of having an effective NRA in a country to regulate and police this, and thereby protect the public.

McCredie (2007) reports that, following the discovery of the association of Thalidomide and birth deformities in Australia and Germany, the product was withdrawn from the United Kingdom (UK) market on the 2nd December 1961. On the 2nd November 1962, a joint sub-committee of English and Scottish Standing Medical Advisory Committees was formed. This sub-committee made the following recommendations (McCredie 2007):

- The responsibility for experimental testing of new pharmaceuticals before they are used in clinical trials remains with the individual pharmaceutical manufacturer.

- It is neither desirable nor practical that the evaluation of new pharmaceutical products be transferred to a central authority.
- There should be an expert body or NRA, to review manufacturer data and offer advice on the toxicity of new pharmaceuticals, whether manufactured in Great Britain or abroad before they are used in clinical trials.

These recommendations are regarded to be control measures to which the NRAs are able to subscribe in order to protect the public from the introduction of unsafe pharmaceuticals into the market. Mader (1994) notes that, under the aegis of the sub-committee, a new system of pharmaceutical regulation was introduced in the UK in 1963. The system was later superseded by the promulgation of the Medicines Act in 1968, which provided stricter statutory control of medicines, including the adoption of GMP. He adds that similar control measures were established worldwide. South Africa was also part of this international trend. The MCC is the NRA established in South Africa in 1965 (Mader 1994).

Thus, the 1901 Diphtheria Tragedy, the 1937 Wonder Drug Tragedy, the 1941 Sulfathiazole Disaster, the 1955 Polio Incident and the 1962 Thalidomide Tragedy were collectively regarded as key trigger events that fundamentally shaped the design of the GMP standard in the global pharmaceutical industry (Patel and Chotai 2008).

Following these tragedies, Resolution WHA20.34 was adopted by WHO in 1966 at the Twentieth World Health Assembly. Resolution WHA20.34 called for quality control of pharmaceutical preparations. The report (World Health Organisation 2014) on Resolution WHA20.34 states that a draft text on GMP was prepared by a group of consultants in 1967. It was submitted to the WHO under the title ‘Draft requirements for good manufacturing practice in the manufacturing and quality control of medicines and pharmaceutical specialities’. This draft later evolved into the WHO-GMP guideline. This guideline is used throughout the world today (World Health Organisation 2014) to ensure that tragic events such as those described in the preceding section do not recur.

The WHO-GMP guideline is of particular importance to this research study because South Africa's MCC-GMP guideline is based on the WHO-GMP guideline. All pharmaceutical manufacturing organisations in South Africa must comply with the MCC-GMP guideline in order to trade. Consistent with the views of Jacobs and Signore (2016), Haleem *et al*. (2014), Jacob (2013), Woodcock (2012), O'Donnell (2008), and Meagher (2006), this study presumes that understanding reasons for the promulgation of GMP assists pharmaceutical organisations with the selection of appropriate Quality Management Practices that do not only comply with regulation, but also ensure that such events never recur. It is envisaged that the conceptual OpEx Model developed by this study for the South African pharmaceutical industry will be aligned with these regulations.

3.2 Quality Management practised in local pharmaceutical organisations

The WHO-GMP guideline forms the basis for GMP guidelines used by NRAs internationally, to regulate pharmaceutical production. Through the activity of regulation, NRAs fulfil their primary function, which is to protect the public (Pharmaceutical Consultancy Service 2016; Mader 1994). A comparison of the views of Baker (2016), Jacobs and Signore (2016), Gupta (2016), Kothari and Patel (2015), Kumar, Tanwar and Arora (2013), Fefer (2012), Olson (2012), Molzon, Giaquinto, Lindstrom, Taminaga, Ward, Doen, Hunt, and Rägo (2011), Medicines Control Council (2010), Coffey (2008), Rägo and Santoso (2008), Mubangiza (2007), Molzon (2005) and Ratanawijitrasin and Wondemagegnehu (2002), confirm that the functions performed by NRAs are a direct solution to quality problems in pharmaceutical manufacturing. From the abovementioned literature, it can be postulated that these functions prevent disastrous events such as the 1901 Diphtheria Tragedy, the 1937 Wonder Drug Tragedy, the 1941 Sulfathiazole Disaster, the 1955 Polio Incident and the 1962 Thalidomide Tragedy from recurring.

The South African NRA, namely the MCC, published a GMP guideline to ensure that all pharmaceuticals marketed in South Africa are safe for their intended use.

This guideline is discussed in Section 3.2.1. The evaluation of this guideline is especially important to this study as all the Quality Management Practices included in the Model designed by this study have to support compliance with GMP.

3.2.1 Good Manufacturing Practice in South Africa

The Medicines Control Council (2010) promulgates the current South African GMP guideline which consists of nine clauses. It provides an organisation's management with guidance in all the different areas of pharmaceutical manufacturing as listed: namely Quality Management, Personnel, Premises and Equipment, Documentation, Production, Quality Control, Contract Manufacture and Analysis, Complaints and Product Recall and Self-Inspection. The orientation of this ensemble of clauses that comprise the South African GMP guideline (MCC-GMP) is understood to have been derived from the tragic events that initially led to the development of GMP.

It is worth noting that twenty supporting annexes on various topics relevant to manufacturing are included in the MCC-GMP guideline, for example, the Manufacture of Sterile Medicinal Products, Manufacture of Medicinal Gases, Sampling of Starting and Packing Material, Computerised Systems and Quality Risk Management inter alia. Key points pertaining to each of the nine clauses of the GMP guideline have been extracted and summarised in the section below. This section of literature examines each clause of the Medicines Control Council (2010) guideline, specifically from a regulatory perspective. Particular Quality Management Practices that are implied or specifically mentioned by the guideline are highlighted, as these practices are regarded as the most important in order to comply with MCC-GMP, and therefore, must be included in the conceptual OpEx Model being developed in this study.

3.2.1a Good manufacturing practice – requirements for Quality Management

In the first clause, the Medicines Control Council (2010) stipulates that the pharmaceutical manufacturer must produce products that are fit for their intended use and that do not place patients at risk. This clause highlights the importance of Risk Management. Furthermore, it also emphasises the cohesive participation of the value-chain where senior management in the organisation is ultimately responsible for product quality and safety, while commitment and participation of employees are essential and the support of suppliers is vital. This foregrounds other important supporting Quality Management Practices such as Employee Training and Supplier Management.

In addition, the clause emphasises the need for an organisation to have a comprehensive and effectively implemented Quality Assurance (QA) system in place. MCC-GMP requires that the system should incorporate Quality Control (QC), Product Quality Review (PQR) and Quality Risk Management (QRM). The system should be fully documented, and its effectiveness monitored. Therefore, it can be concluded that to ensure compliance with this clause of MCC-GMP, the conceptual OpEx Model developed by this study must consider elements of QC, Employee Training, Supplier Management, PQR and QRM.

3.2.1b Good manufacturing practice – requirements for Personnel

In the second clause of MCC-GMP, the Medicines Control Council (2010) states that an effectively operating QA system depends on personnel who are suitably qualified to perform all the necessary tasks. The responsibilities of the personnel should be documented and clearly understood. All personnel should be aware of the principles of MCC-GMP and receive initial and continued training relevant to their needs. The foregoing section further bolsters the importance of Employee Training, and this will be considered during the development of the conceptual OpEx Model.

3.2.1c Good Manufacturing Practice – requirements for premises and equipment

Clause three of the guideline details the specifications required for the general pharmaceutical manufacturing and ancillary areas in the manufacturing process. The Medicines Control Council (2010) requires that the general premises and manufacturing equipment should be cleaned according to detailed written procedures, foregrounding the importance of Standard Operating Procedure (SOP) Management. Furthermore, MCC-GMP provides prescriptions for the maintenance and control of equipment and mentions that no unauthorised personnel are allowed in certain areas. Therefore, this clause is regarded as accentuating the importance of Maintenance Management and QRM.

3.2.1d Good Manufacturing Practice – requirements for documentation

Clause four of the Medicines Control Council (2010) states that 'good documentation' constitutes an essential part of the QA system. Compliance to MCC-GMP necessitates that all documentation used during quality management be legible and free of errors. This clause provides guidance on four broad categories of documents namely 'specifications'; 'manufacturing formulations, processing and packaging instructions'; 'procedures' and 'records'. In understanding this clause, the association between good documentation and SOP Management, Supplier Management and PQR is highlighted.

In line with the document requirements of other quality management standards such as ISO9001: 2015, Calabrese, Trotter and Foo (2016) state that the document requirements for compliance with GMP are aligned with the requirements of other quality management standards. From this, it is understood that any document requirements for conceptual OpEx Model developed for the South African pharmaceutical industry must be designed in a manner that ensures that all the MCC-GMP requirements are met.

3.2.1e Good Manufacturing Practice – requirements for production

Clause five of the MCC-GMP guideline delineates stipulations for the pharmaceutical production process. The Medicines Control Council (2010) stipulations on productions state that activities must take place according to clearly defined procedures. Thus, this study deduces that SOP management is required. Any deviation from procedures should be avoided if possible. However, if needed, changes may be approved in writing by a competent person with the involvement of the Quality Department. This practice is referred to as Deviation Management. Furthermore, significant amendments to the manufacturing process should be validated prior to implementation. This practice is referred to as Change Control Management.

Based on the guidance in this clause provided by Medicines Control Council (2010), it is understood that multiple concurrently performed Quality Management Practices are required in a pharmaceutical manufacturing facility to ensure successful compliance to MCC-GMP. These include, but are not limited to, SOP management, Supplier Management, Employee Training, Deviation Management, CAPA management, Change Control Management, Risk Management, Maintenance and Self-inspection.

3.2.1f Good Manufacturing Practice – requirements for Quality Control

Clause six underscores the importance of QC as a component of quality management in pharmaceutical organisations. The Medicines Control Council (2010) stipulates that the organisation should make adequate resources available to ensure that all QC requirements are effectively and reliably performed. From this clause, it was also concluded that Quality Management Practices that capacitate QC should not be confined only to the final products tested. Rather, QC is essential during the entire manufacturing process. Furthermore, MCC-GMP states that a person from the Quality Department of the organisation must always be involved in all decisions which potentially concern the quality of pharmaceutical products. Importantly, a sampling of products should take place in accordance with written procedures and analytical methods should be validated. Specific QC documentation is required for sampling, testing and on-going stability of pharmaceutical products programme. Thus, common Quality

Management Practices which would be associated with the aforementioned include SOP management, Employee Training, CAPA Management, Deviation Management, Change Control Management, PQR and QRM.

3.2.1g Good Manufacturing Practice – requirements for contract manufacture and analysis

Principles of contract manufacture and analysis of products are provided by Medicines Control Council (2010) GMP guideline clause seven. This clause is the only clause that does not make any direct reference to functions in the pharmaceutical organisation that require specific Quality Management Practices. It outlines the responsibilities of the contract giver and the contract taker when pharmaceutical products are produced by a third party manufacturer.

3.2.1h Good Manufacturing Practice – requirements for complaints and product recall

The Medicines Control Council (2010) promulgated an unabridged clause, called clause 8, which dealt with complaints and product recall. The rationale behind clause eight is believed to be a reaction to the 1941 Sulfathiazole Disaster and the 1962 Thalidomide Tragedy. This clause mandates that all complaints and other information concerning potentially defective products must be reviewed carefully, according to a written SOP. At least one delegated person from the QC department should be involved in the evaluation of complaints and product defects. When a complaint is received, the organisation should determine if the complaint is valid and take appropriate action to remedy the situation. Thus this clause also underscores the vital importance of appropriate Quality Management Practices in pharmaceutical manufacturing. The following Quality Management Practices associated with this clause are SOP management, CAPA management and QRM.

3.2.1i Good Manufacturing Practice – requirements for self-inspection

O'Donnell (2008) is of the opinion that the aim of Self-inspection in pharmaceutical organisations is to avert GMP deficiencies and potential product recall. From this perspective, the final Medicines Control Council (2010) clause on Self-inspection is considered to offer 'risk-based' guidance. Self-inspections

may be regarded as a form of QRM. The Medicines Control Council (2010) states that the pharmaceutical organisation needs to ensure that internal audits are conducted at regular intervals and also states that it is imperative that internal audits should be conducted by competent and trained persons. Thus, Quality Management Practices associated with this clause are Self-inspection, QRM and Employee Training.

3.3 Quality Management Strategies and Operational Excellence

The previous section draws attention to a number of compulsory Quality Management Practices that are required, to comply in the highly regulated pharmaceutical industry and thereby, simultaneously meets the first objective of this research study. Significantly, Willag (2001) argues that stand-alone Quality Management Practices which are performed merely to comply with GMP are essentially a bureaucratic exercise if they are not strategically linked to business objectives. Therefore, this chapter proceeds with a discussion on the manner in which selected Quality Management Practices are used as components of a Quality Strategy, to not only comply with GMP but, concurrently, to pursue excellence in operations (OpEx) in pharmaceutical organisations as well. The design and purpose of various commonly used Quality Management Strategies are thus presented in this section.

A broad review of literature on Quality Management Strategies discussed by Lembke (2017), Alhuraish, Robledo and Kobi (2016), Cherrafi, Elfezazi, Chiarini, Mokhlis and Benhida (2016), Jensen (2016), Bhonsale, Telen, Stokbroekx and van Impe (2016), Alotaibi (2014), Oakland (2014), Basu, Friedli and Bellm (2013), Friedli and Bellm (2013b), Friedli, Mänder and Bellm (2013), Mazumder, Bhattacharya and Yadav (2011), Baines (2010), Goetzfried, Friedli and Guetter (2010), and Migliaccio, Ricciardi, Scott and Winskill (2010) directed this research to consider that there is no solitary or uniform view on the best Quality Management Practices to support business performance and regulatory requirements in the global pharmaceutical industry. These varied literature sources imply that pharmaceutical organisations manage to successfully employ

different Quality Strategies guided by the requirements of their divergent business objectives.

The most common Quality Management Strategies deployed in the global pharmaceutical industry in the last ten years, in an attempt to secure sustainable OpEx, are TQM, Total Productive Maintenance (TPM), Just in Time (JIT), Quality by Design (QbD), Six Sigma, Lean and Right First Time (RFT). A concise description of each of these strategies is presented below, together with a detailed comparative table (Table 3.1) which enables this study to determine similarities between the strategies and identify the most common Quality Management Practices used within these strategies. Through this comparison, the second objective of this study, which is to conduct an explorative literature study on OpEx strategies used in the global pharmaceutical industry, is met. Furthermore, this comparative analysis allows this study to evaluate the strategies with a view to identifying feasible Quality Management Practices that may be included in a conceptual Model that this study has envisaged to developing as objective five.

3.3.1 Total Quality Management

Total Quality Management is portrayed by Lembke (2017) and Friedli and Bellm (2013b) as a rigorous problem-solving approach that is based on fact and whose core elements include Process Management, Customer Integration, Supplier Quality Management and Cross-functional Product Development. Goetzfried, Friedli and Guetter (2010) describe TQM as the top-down adoption of a philosophy of excellence, focused on the customer, people and supplier development and continuous process improvement, where an organisation incessantly strives for continuous improvement across the entire organisation. Mazumder, Bhattacharya and Yadav (2011) attest that TQM requires an organised effort from the entire organisation to prevent and eliminate errors at every stage of production. They argue that the assurance of quality in pharmaceutical products involves the input of many departments and disciplines within a pharmaceutical organisation.

Consistent with Mazumder, Bhattacharya and Yadav (2011), Baines (2010) emphasises the importance of interdepartmental collaboration in TQM. He argues that departments in pharmaceutical organisations should work as a unit, rather than as disparate entities within the same organisation. This implies that TQM can be regarded as an Organisational Strategy, as opposed to merely a Quality Management Strategy.

Quality Management Practices commonly associated with TQM in the pharmaceutical industry are SOP management, Employee Training, Deviation Management, CAPA Management, Change Control Management, Supplier Management and Self-inspection. In light of the aforementioned, TQM is regarded as a Quality Management Strategy that can be aligned with business objectives and thereby presumed to be a suitable strategy in an endeavour to attain OpEx in a pharmaceutical organisation.

Finally, Friedli and Bellm (2013b) and Goetzfried, Friedli and Guetter (2010) advises that TQM allows for the easy integration of other quality strategies. They propose that other strategies, which can be stand-alone strategies, are also capable of being integrated into TQM. These include TPM, JIT and Six Sigma.

3.3.2 Total Productive Maintenance

Lembke (2017) refers to TPM as a strategy that focuses on the appropriate use of technology and maintenance. The pharmaceutical industry is a capital intensive industry with a large part of its fixed assets tied up in plant facilities and equipment making maintenance a crucial element for an efficient production environment. This strategy can be effortlessly integrated into a TQM strategy. Friedli and Bellm (2013b) moot that the concept of TPM is based on all employees learning how to clean, inspect and maintain equipment. Efficient usage of these resources reduces the capital employed. Stable running machines and equipment support the design of stable processes and adherence to plans. Goetzfried, Friedli and Guetter (2010) postulate that preventive maintenance, technology assessment and usage and housekeeping are enablers of TPM. From this literature, it can be gleaned that TPM cannot be used as a stand-alone

strategy to attain OpEx since it does not take a number of important GMP requirements, for example, supplier management, PQR and self-inspection into consideration.

3.3.3 Just In Time

Oakland (2014) proposes that another common global strategy, namely JIT, is a move away from demand-driven production towards forecast driven production. An organisation needs to collect data on the manufacturing process to actively to make this transition. Notable features of the JIT strategy are the use of Kanban cards and standardised containers during manufacturing, which represent a form of visual management. Friedli and Bellm (2013b) forewarn that JIT will not be successful unless the manufacturing process is already stable and virtually free of variation. This is considered to be a challenge in South Africa since the Department of Trade and Industry of South Africa (2017) confirms that the South African pharmaceutical industry is manual labour intensive, and therefore, variability in the production process is high (Gordon 2011).

A further challenge with JIT, according to Friedli and Bellm (2013b), is that pharmaceutical manufacturing processes are not heterogeneous in the sense that a typical manufacturing facility operates several different types of dosage form processes (for example, vaccines, syrups, powders, tablets and capsules) simultaneously. This situation imparts an inherent degree of variation in pharmaceutical manufacturing. Despite this, Friedli and Bellm (2013b) maintain that pharmaceutical organisations are able to gain some value with JIT by eliminating process waste such as over-production, excess raw materials and unnecessary movement in a pharmaceutical plant.

Parallels observed in the views of Oakland (2014), Friedli and Bellm (2013b) and Goetzfried, Friedli and Guetter (2010) JIT is a strategy that cannot be used in isolation. JIT entails process management based on facts, customer focus, focus on the reduction of variation and waste and improved communication. However, they believe that JIT lacks a strategic or leadership element. Thus, this study

deduces that JIT should be used in combination with another strategy, for example, TQM.

3.3.4 Quality by Design

Quality By Design (QbD) is depicted by Bhonsale et al. (2016) as a scientific, holistic and risk-based approach towards process management and pharmaceutical development. According to Basu, Friedli and Bellm (2013), Supplier Management is also an element of QbD since it evaluates input materials and input process parameters. QbD strives to eliminate process variability caused by the aforementioned inputs, on the basis of factual data obtained from the process. This strategy then uses a feedback loop to secure continuous improvement and thereby improve customer focus.

Basu, Friedli and Bellm (2013) investigated efforts made by various pharmaceutical organisations to implement QbD and concluded that the implementation of QbD requires a full understanding of the process by everyone on the manufacturing floor. This includes interactions between variables that influence production, the impact of raw material variability on the quality of the intermediate products and the final product. Intensive and continuous training is, therefore, a feature of QbD. Consequently, QbD is an expensive and time-consuming strategy. Kenett, Steinberg and Reiner-Benaim (2015) and Basu, Friedli and Bellm (2013) caution that only a few organisations in the world would have the knowledge and resources to implement this strategy fully. This study infers that QbD is important in pharmaceutical manufacturing, in terms of pharmaceutical development. Based on the preceding discussion, however, it is concluded that QbD is not suitable for inclusion in a conceptual OpEx Model for general South African pharmaceutical manufacturers since it is too expensive and time-consuming to sustain.

3.3.5 Six Sigma

Alhuraish, Robledo and Kobi (2016) and Cherrafi *et al.* (2016) state that Six Sigma is a structured five phase problem-solving strategy that is used in conjunction with associated performance metrics to measure project completion. The five phases are collectively referred to as the DMAIC cycle, each letter representing one phase of the cycle, namely Define, Measure, Analyse, Improve and Control. Six Sigma is described as a 'system' in which decisions are taken to ultimately achieve the strategic objectives of an organisation. They argue that organisations that have truly internalized the principles of Six Sigma continuously isolate and eliminate variables that cause deviation. Six Sigma is strongly orientated on the statistical measure of standard deviation (Friedli and Bellm 2013b), also known as 'sigma' in processes, and the fundamental goal of Six Sigma is to strive towards zero defects through monitoring deviations and the subsequent reduction of variation the organisations. Thus, SOP Management, Employee Training, Deviation Management, CAPA Management and PQR are features of a Six Sigma Strategy. These data-driven Quality Management Practices continuously enable the organisation to improve its processes. Visible leadership, a participative honest supporting culture, tools to drive responsiveness such as Lean or TPM, are additional vital ingredients for a Six Sigma strategy to be successful in an organisation.

Research by Werani, Friedli and Gronauer (2010) portray Six Sigma as a highly successful Quality Management Strategy in pharmaceutical organisations in the global context. They claim that the DMAIC cycle provides an excellent structure for problem-solving and for process improvement in a pharmaceutical manufacturing organisation. In contrast, Cherrafi et al. (2016), suggest that Six Sigma lacks a theoretical underpinning to be used as a solitary overall Organisational Quality Strategy. This view is notably consistent with Cone (2017) and Wyatt (2018), who argue that Six Sigma can never be regarded as a stand-alone strategy to secure quality, continuous improvement or OpEx in an organisation. The weaknesses of Six Sigma are rooted in its minimal consideration of the human behavioural and team-participative elements. Wyatt (2018) suggests that these important elements are essential for creating and

driving sustainable change. Ultimately this research concludes that Six Sigma is not a suitable quality strategy for sustainable overall operationally excellent business performance in the South African context since the South African pharmaceutical industry is predominantly manual and labour intensive (Department of Trade and Industry of South Africa 2017).

3.3.6 Lean

Cherrafi *et al.* (2016) and Friedli and Bellm (2013b) argue that a Lean quality strategy's primary objective is to produce products or services of higher quality at the lowest cost by eliminating waste. They define waste as anything other than the absolute minimum amount of time, production space, storage space, raw materials, equipment or parts required to produce a product. All non-value adding operations have a direct impact on performance, quality and cost. The authors suggest that a Lean strategy relies on Quality Management Practices that have a strong focus on the elimination of variation during process management, continual improvement and customer satisfaction such as SOP Management, Employee Training, Deviation Management, CAPA Management, Supplier Management, PQR and Maintenance.

Cherrafi *et al.* (2016) point out that an additional and distinctly useful Quality Management Practice employed by Lean is Visual Management through the use of Kanban cards. Jensen (2016) and Friedli, Mänder and Bellm (2013) consider value stream mapping and Kaizen workshops (also referred to as Quality Circles) to be part of a Lean strategy. It can be deduced that a Lean strategy is characterised by an emphasis on leadership, strategy, maintenance and people empowerment through training and problem-solving, and is, therefore, regarded as a superior Quality Management Strategy in pharmaceutical manufacturing.

3.3.7 Right First Time

RFT is a strategy that aims to create a culture of continuous improvement and promote leadership behaviour in all employees (Mangal 2016; Migliaccio *et al*. 2010). Thus, an important distinguishing trait of RFT is its strong alignment with the business strategy of an organisation. The design of the RFT strategy allows

it to be specifically tailored to aid the organisation using quality management, in order to achieve OpEx within the parameters of the organisation's business strategy.

In support of Migliaccio *et al.* (2010), Mangal (2016) claims that the enculturation of RFT by a pharmaceutical organisation represents a shift from such reactive testing to a more pro-active approach, where all employees assume accountability, and quality is built and integrated into products and processes. Risk management is, therefore, a prominent Quality Management Practice in this strategy. RFT strategy has four levels that an organisation progresses through in order to attain operational excellence. Migliaccio *et al.* (2010) clarify that the first RFT level is attained if an organisation merely complies with regulatory standards. In the second level, data derived from Quality Management Practices such as deviation management and CAPA management is used to understand the manufacturing processes scientifically in a risk-based approach.

The third RTF level is known as the 'improvement' level. Migliaccio *et al.* (2010) advise that this level involves the elimination of waste in an organisation. When an organisation reaches the fourth level of RTF, it is able to employ tools and techniques that are traditionally and commonly associated with Six Sigma, to eliminate the root causes of deviations, as well as Lean, to eliminate waste. It is noted that the application of RFT uses identical tools to other quality strategies. He suggests that individual strategies are referred to by different names in different organisations, yet the same key concepts and basic fundamental tools are applied during different individual strategies, in order to achieve the goal of OpEx.

Ultimately this study concludes that there is not one particular or distinct quality strategy that can be regarded as the panacea to attain OpEx in a pharmaceutical organisation, as seen in Table 3.1. This supposition is aligned with the view of Prajogo and Sohal (2006), which is that it is indeed possible to customise a melange of Quality Management Practices for a particular purpose. The conceptual OpEx Model developed by this study will constitute the foundation of

a strategy intended for use by pharmaceutical manufacturing organisations in South Africa.

Table 3.1 Comparison of internationally used Quality Management Strategies in the pharmaceutical industry (Developed by the Researcher)

Quality Management Strategy and name/s of an organisation that successfully deployed the strategy	**Most significant features**	**GMP mandated Quality Management Practices**	**Examples of Quality Management Practices associated with this strategy that are not mandated by GMP**
Total Quality Management Tadeka (Japan) (McColgan 2013)	Philosophy of excellence; Customer focus; Continual process improvement; People and supplier management	SOP management Supplier management Deviation management Training CAPA management Change control management Quality risk management Periodic quality review Maintenance Self-inspection	Material and information management. Balanced scorecard Change management Best practice transfer Process optimisation
Total Productive Maintenance Genentech Inc. (Europe) (Griffith, Rondoletto and Hamel 2010)	Focus on the use of technology and maintenance to manage quality	SOP management Deviation management Training CAPA management Change control management Quality risk management Maintenance Self-inspection	Overall equipment effectiveness (OEE)

Just In Time Nycomed - acquired by Tadeka (Japan) (McColgan 2013)	Customer focus; Fact-based process improvement; Reduction of variation and waste.	SOP management Deviation management Supplier management Deviation management Training CAPA management Self-inspection	Manufacturing execution system (MES) Enterprise manufacturing intelligence (EMI)
Quality By Design Novartis (Europe) (Bisson, Guetter and Gronauer 2010)	Risk-based (fact-based) planning; Reduction of variation and waste; Supplier management; Continual process improvement	SOP management Supplier management Training CAPA management Quality risk management Self-inspection	Validation management Quality function deployment (QFD) Quality target product profile
Six Sigma Genentech Inc. (Europe) (Griffith, Rondoletto and Hamel 2010)	Fact-based continual process improvement; Reduction of variation; Customer focus	SOP management Deviation management Training CAPA management Quality risk management Self-inspection	Statistical process control (SPC) Process capability management Design of experiments Validation management
Lean Amgen (United States) (Coffey 2008)	Fact-based continual process improvement; Reduction of waste; Customer focus	SOP management Supplier management Training CAPA management Change control management	Hoskin Kanri Data integrity management Visual management Poka yoke Value stream mapping

		Maintenance Self-inspection	
Right First Time Pfizer (Europe and the United States) (Seller and Davis 2013)	Focus on leadership of the organisation to drive quality; Employee empowerment; Risk-based continual process improvement; Reduction of variation and waste	SOP management Supplier management Deviation management Training CAPA management Change control management Quality risk management Periodic quality review Maintenance Self-inspection	Value analysis Creating Flow 5S and visual workplace management Setup reduction management

3.4 Chapter summary

The historical context around the origins of regulation in the global pharmaceutical industry is presented in this chapter, with justifications for the promulgation of GMP. The structure of GMP is discussed, and the most common global Quality Management Practices required to comply with GMP are highlighted. The interdependent nature of Quality Management Practices in the pharmaceutical industry emerges from this discussion. Each Quality Management Practice has its unique function. However, individual Quality Management Practices not only support but also enable other practices. Furthermore, the adequate and effective functioning of one practice depends on the successful functioning of others.

Thereafter, this chapter proceeded with the exploration of various Quality Management Strategies that incorporate a selection of Quality Management Practices, aligned with GMP in order to drive the progress of quality and simultaneously achieve operational and business success. This study concludes that a number of strategies have been designed to manage quality and that some strategies are equally capable of actualising OpEx. The next chapter entails a comparative study on pharmaceutical industries in the three founder member ICH tripartite countries. An OCAI cultural research lens enables the scrutiny of the underpinning culture of each geographical region and highlights tensions that emerge during each ICH region's transition to OpEx.

CHAPTER FOUR
A TALE OF THREE REGIONS

'On production floors and in corporate offices, sociological verbiage has replaced a basic understanding of human behaviour.'

- Dr William Edward Deming

Chapter Four returns the focus of this study to the concept of culture. The previous chapter was a necessary departure from the concept of culture to provide insight into the onerous regulatory context of the pharmaceutical industry, which has a direct influence on all manufacturing operations in pharmaceutical organisations. The OCAI cultural analysis tool that was discussed in Chapter Two provides this study with a research lens to evaluate the ICH tripartite (Japan, Europe and the United States) from an Activity Theory perspective. The aim of this cultural examination is to provide an analogous but comparative view of important features associated with quality management during the activity of pharmaceutical production in each of the three countries to meet the third research objective of this study, which is to perform a literature examination of the three founder member regulatory authorities of the International Council for Harmonisation (ICH) namely, Japan, Europe and the United States.

All literature sources examined in this comparative analysis evaluate the pharmaceutical industry from a distinctly different perspective to that considered by this chapter. The literature sources that were examined were written for a different purpose and unlike that of this comparative study. This exploration sets out to examine the underpinning cultural context in the three different ICH regions from a fresh perspective, which has not been attempted previously. It should be noted that this study is contextual and is not intended to identify transferable Quality Management Practices, even though ICH regions are compared. The intention is rather to examine the influence of culture on pharmaceutical production and draw inferences on how culture can add value to a South African Model of Quality Management Practices toward OpEx in the pharmaceutical industry. Extensive publications are examined, and publications were selected

on the basis of their value, their explanatory power and importantly, only if the same type of publications could be found in all three regions.

4.1 Activity Theory

An Activity Theory research approach is adopted for the comparative study component of this doctoral study to ensure that a consistent formal, structured approach is used to analyse the three geographical ICH regions. Engeström (2014) and Hashim and Jones (2007) attest that Activity Theory is an ideal approach for studying a situation from a cultural perspective since it renders a robust framework for a cultural examination to take place. Activity Theory offers a holistic and contextual method of discovery which is especially valuable in a qualitative enquiry on culture. There are seven elements in the Activity Theory framework as depicted in Figure 4.1. During an Activity Theory examination, the researcher specifies three known elements pertaining to the problem at hand, in order to explore the remaining four elements. The known elements are the subject who performs the activity, the activity which takes place and the goal of the activity. In this comparative study, the three geographical ICH regions are the subject, pharmaceutical production is the activity, and the goal of the activity is OpEx.

The unexplained elements are the tools that are used during the activity, the rules or norms regulating the activity, the stakeholders that play a role in the activity and the division of labour that affects the activity. Activity Theory adds practical value in understanding a situation by defining each element in a systematic review process and then exposing the interfaces between the elements, as seen in Figure 4.1. Contradictions, tensions or problems within the elements and between the various elements are identified. Ekundayo, Wang and Andrade (2012) refer to the contradictions and tensions as "*agents of change*" and the "*root causes for innovation*". They serve as triggers for development and are good for the continuous improvement of the system in which activity takes place. In this study, any contradictory OCAI cultural values that have an influence on pharmaceutical production will be highlighted. Before the activity of

pharmaceutical production in the ICH tripartite is examined, a very brief background to the ICH is provided.

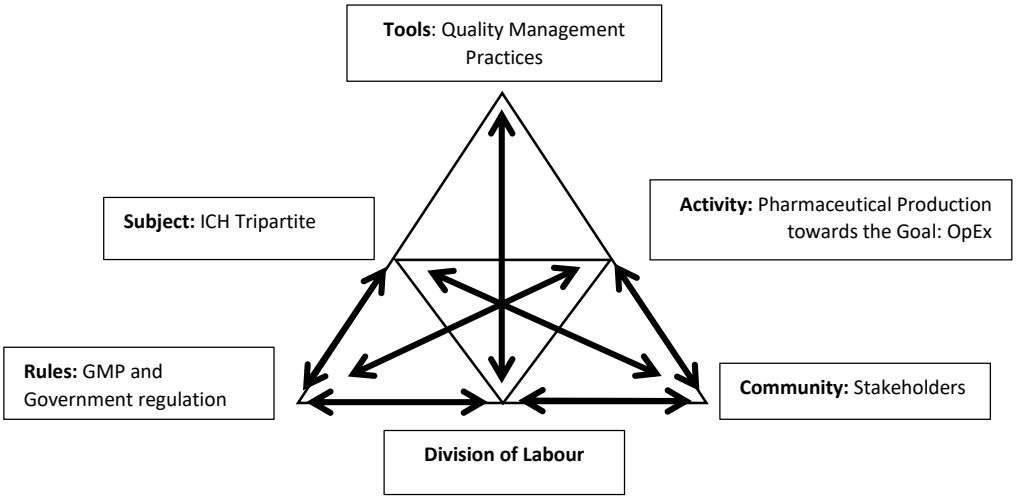


Figure 4.1 Activity Theory Framework (Adapted by the Researcher)

4.2 Background to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

The ICH is the most widely recognised international association of pharmaceutical stakeholders (Shrey, Bodla, Shweta, and Pathak 2014), and best known for their efforts to harmonise global pharmaceutical regulation. Coffey (2008) elucidates that the ICH originally consisted of the three biggest market segments that historically dominate the global pharmaceutical industry, namely the United States, Europe and Japan. The United States is the largest segment and accounted for 50 per cent of global sales in 2007, while Europe accounted for 28 per cent and Japan for 14 per cent. The remaining 9 per cent of global sales is accounted for by emerging markets including other Asian countries, Africa, Australia and Latin America.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (2018) recounts that the move towards the harmonisation of regulatory requirements was pioneered by the European community in the 1980s. The aim of this harmonisation was the development of a single global market for pharmaceuticals. Prior to the 1990s, pharmaceutical

organisations across the globe were experiencing difficulties in marketing their products in different countries, due to differing regulatory expectations. Thus the primary purpose of the ICH was identifying ways in which greater harmonisation could be achieved in the interpretation and application of technical guidelines and requirements for product registration and pharmaceutical production. This purpose is rooted in the desire for more economical use of resources and the elimination of unnecessary delays in the development and availability of new medicines.

In the 1980s, discussions between Japan, Europe and the United States on the possibilities for harmonisation, ensued (McCormick 2009). The result of these discussions led to a joint regulatory-industry initiative on international harmonisation, conceived in Paris in 1989. For practical reasons, for the purpose of this study, the UK and Switzerland are considered to be part of Europe as they are a part of that geographical region. The ICH originally consisted of regulators and research-based industry representatives from Japan, Europe and the United States, and was formally set up in 1990 as a joint forum between regulatory bodies and organisations in the pharmaceutical industry. McCormick (2009) reports that since its inception, the ICH strove to develop and publish guidelines on Quality Management Practices which are suitable for direct use by industry. The remainder of this chapter will follow an Activity Theory framework to comparatively examine features of the pharmaceutical industry in the original ICH tripartite and conjecture on the manner in which the OCAI culture types support operation in those pharmaceutical industries.

4.3 Activity Theory examination of pharmaceutical production in the ICH regions

The primary objective of this comparative study is to uncover any common features, distinctions and dichotomous aspects associated with the ICH regions. The purpose is to highlight generic pitfalls that arise due to cultural influences so that these can potentially be avoided when the conceptual Model of Quality Management Practices is designed for South African organisations. Simultaneously, this study will illuminate areas where culture promotes OpEx in

pharmaceutical production. During this analysis, industry traits that are presumed to be supported by one (or more) OCAI culture types will be highlighted and examined. The structure of this study is determined by the limited amount of literature available on Japan's pharmaceutical industry, in particular. This is consistent with Umemura's (2008) findings that a significantly small number of publications on the Japanese pharmaceutical industry were written. Only literature sources that enabled the comparison of all three geographical regions could be used to conduct this comparative study.

4.3.1 Tools for OpEx

On the premise provided by Chapter Three, which highlighted the inherently rigid regulatory nature of the pharmaceutical industry, this study presumes that the basic quality management tools mandated by GMP are used in pharmaceutical organisations in Japan, Europe and the United States, and that these are similar since GMP is legislated in all three geographical ICH regions. This study is unable to confirm the names of the specific Quality Management Practices employed in Japan due to the unavailability of specific literature on Quality Management Practices in the Japanese pharmaceutical industry. The reason for the limited amount of public information on the practices as proposed by Umemura (2008), is the Japanese pharmaceutical industry's characteristic strong domestic orientation. She suggests that traditionally Japanese people are primarily concerned with their internal affairs, and therefore, do not see the need to publish literature on their work for the general public. This is compounded by the ranked nature of the Japanese society in general. According to Umemura (2008), three distinct root causes for not publically sharing information are Japanese Government Policy, the industrial structure of the pharmaceutical industry and Japanese Medical Culture. Based on these it is presumed that the Japanese pharmaceutical industry has a very strong hierarchical orientation.

Notwithstanding the preceding commentary, Japan Pharmaceutical Manufacturers Association (2015) reports that Japan's Ministry of Health, Labour and Welfare (MHLW) (formerly known as the Ministry of Health and Welfare (MHW) actively works with Japanese pharmaceutical organisations to guarantee

a high-level of implementation of internationally recognized GMP rules. Thus, an assumption is made that selected quality management tools, as outlined in Chapter Three of this research, may be integral to operations in Japanese pharmaceutical organisations, to ensure and promote international standardisation and conformity in GMP. Moreover, Corriero (2018) and Mangal (2016) argue that Japan has garnered a reputation as leaders in Quality Management Practices since Japanese manufacturing organisations have developed internationally recognised quality strategies with quality management tools such as Quality Circles, 5S, Poka Yoke, Kaizen Opportunities, Hoskin Kanri and Lean, which entails SQC, top-down participation and employee involvement.

From this point of departure, it can be assumed that a hierarchical culture underpins standard operating tools in Japanese quality management, considering that all these tools are very structured. Cognisance is also taken of GMP, which mandates the use of selected quality tools in all ICH geographical regions (Corriero 2018) and that these are orientated chiefly towards control, efficiency, consistency and uniformity. Control orientated values are, however, particularly compounded in Japanese organisations where the bureaucratic influence of government protectionist policies towards the pharmaceutical industry also plays a significant role (Umemura 2008).

As this study's focus shifts to tools used in European pharmaceutical organisations, a stark contrast is noted between the bureaucratic, inward focused and relatively closed Japanese pharmaceutical industry (Ribbink 2016; Pomeroy 2013) and the European pharmaceutical industry. Minnock (2017) expounds on the nature of the European pharmaceutical industry with a claim that the top ten pharmaceutical organisations in Europe in 2017, are multinational organisations even though they originated in Europe, for example, Merck and Roche. This foregrounds harmonisation of Quality Management Practices, which supports the increasing trend of internationalisation of pharmaceutical organisations. Literature (Carpintero, Morán, Pretto, Reddy and Telpis 2017; Lembke 2017; Cherrafi *et al.* 2016; Basu 2013; Friedli and Bellm 2013b; Seller and Davis 2013; Crossman 2010; Migliaccio *et al.* 2010; Griffith, Rondoletto and Hamel 2010) suggests that a melange of tools are used by European pharmaceutical

organisations, in addition to those prescribed by GMP. The tools for OpEx include Lean, cLean (current Lean), RFT, Six Sigma and a combination of JIT, TPM and TQM.

Two prominent features that emerge from the evaluation of the European cases mentioned are that there is an integration of a variety of quality management tools in the organisation's business strategy and that substantial value is placed on people management. This is aligned with the high-level structure of the most prestigious quality award in the European region, namely EFQM, which also confirms that these are valued features in quality management. 'Policy and strategy' and 'people' are denoted as enablers in the EFQM award criteria, and 'people' are considered a valuable resource in quality strategies adopted by European organisations. The organisation's workforce creates value; therefore, the organisation has the responsibility of training and rewarding employees to increase their motivation, well-being and satisfaction (Friedli and Bellm 2013a). Thus, clan culture predominantly supports Quality Management Practices in European organisations.

The United States literature on the pharmaceutical industry (Shanley 2017a; Shanley 2017b; Shanley 2017c; Nenni, Giustiniano and Pirolo 2014; Friedman 2012; Coffey 2008; Kickuth and Friedli 2006) is similar to the European region, where a variety of Quality Management Practices are used as tools within OpEx strategies. These tools are CAPA management, Change Control Management, Management Review, Process Performance and Product Quality Monitoring System within TQM, Lean, Six Sigma and RFT. A common feature noted in all the cases examined in the United States pharmaceutical industry is a threefold emphasis on 'business strategy' 'people' and 'operations', which is a progression from only 'strategy' and 'people' in the European region.

Shanley 2017a, Shanley 2017b and Shanley 2017c argue that in the United States, in particular, OpEx strategies must be agile and relevant in order to be successful, and must meet customer demand and the needs of the business. Furthermore, Friedman (2012) argues that Quality Risk Management and training are enablers that must be ingrained in an organisation's mindset and are

important in daily decision making. He regards the United States pharmaceutical industry as a successful global leader in OpEx. He mentions, however, that consideration of culture is required in United States organisations to sustain success. This literature suggests that a requirement for success in the operations sector in pharmaceutical manufacturing in the United States is a degree of hierarchy and clan culture together with a degree of innovation and market-driven culture. A deduction is made that a balanced underlying culture is the best approach to support the implementation and maintenance of quality management tools for OpEx, and the United States region serves as evidence that a balance of all these cultural archetypes does support OpEx.

4.3.2 Rules and regulations

Firmly rooted in the requirements of GMP and as presented in Chapter Three, Meagher (2006) describes the pharmaceutical industry as an environment with onerous regulatory requirements that has an impact on quality management. The role of the ICH in this environment is merely to provide guidance and promote harmonisation to foster international trade. The legal requirements are promulgated by NRAs and governments in the respective regions.

Notification of GMP took place in Japan in 1974 (Naruse 2015), which was synchronous with the global trend observed in pharmaceutical manufacturing in the 1970s. Significantly, another six years elapsed before GMP officially became legislation in Japan. This late adoption of GMP, as argued by Meagher (2006), is due to Japan's politicised, unscientific and non-transparent governmental policies on the pharmaceutical industry under the custodianship of MHW. Umemura (2008) concurs with Meagher (2006) that a consequence of the total devastation of Japan's entire industrial sector due to World War II was that the Japanese Government adopted a very controlling stance with regard to the pharmaceutical industry in particular. Even though this industry caught up with the Western world by the 1970s; the MHW and the Japanese Government continued to maintain a very protective stance towards pharmaceutical organisations and legally restricted foreign competition from entering the Japanese market. Simultaneously, public health agendas were prioritised to

ensure low-cost medication for the Japanese population. Takenaka (2017), Ribbink (2016) and Umemura (2013) state that the unintended disadvantage of protective governmental regulation of Japanese pharmaceutical organisations stifled development in the Japanese pharmaceutical industry. Subsequently, the ability of Japanese pharmaceutical manufacturers to compete with their western counterparts was compromised. The authors believe that global pressure through the ICH was a key factor that eventually propelled Japan to consider a more open approach to pharmaceutical trade in the 1990s. This study regards this as evidence of a very hierarchical culture permeating Japanese society and impacting on pharmaceutical manufacturing.

With regard to rules and regulations, this study notes a similarity between the differences observed between Japan and Europe, when examining quality management tools. In the European region, the regulatory system is overseen by the European Medicines Regulatory Network which is a partnership between four primary stakeholders namely: the European Commission (EC), the European Medicines Agency (EMA), European Economic Area (EEA) and NRAs in European Union (EU) member states. This regulatory system has a consistent region-specific approach to the regulation of pharmaceutical products in greater Europe (European Medicines Agency 2016); thus it lends itself towards a clan orientation. The system promotes quality management (Salmonson 2016) and facilitates the exchange of information between stakeholders on, GMP inspections, among others, to help control pharmaceutical production in the region. The success of this system is contingent with supportive legislation within member countries. In addition to the 28 EU member states, three other countries in the European ICH region are part of the network of stakeholders. Allchurch (2016) underscores that GMP is a platform for quality management from which all parties in the network connect to harmonize regulation and promote transparency. The NRAs work closely with EMA and EEC. They meet four times a year to discuss strategic issues around regulation, best practice, information technology (IT) considerations and ultimately aim to streamline processes and operations. This demonstrates a clan approach to regulation and quality management in the European region.

Directing the research lens towards the United States, Coffey (2008) asserts that the United States pharmaceutical industry is the largest in the world and that they are also the only pharmaceutical industry that is not directly government regulated. Hu, Scherngell, Nga Man, and Wang (2013) confirm that the United States is globally dominant and leads the way in terms of regulation of the global pharmaceutical industry. The primary body regulating the United States pharmaceutical industry is the internationally recognised FDA (United States Food and Drug Administration, 2018a), which is a federal agency of the United States empowered by the Department of Health and Human Services. They are a consumer protection agency and the custodian of GMP in the United States, and they develop regulation based on government laws. Furthermore, Hu *et al.* (2013) state that the FDA is internationally recognised as a stringent protector of the American public; however, they are also regarded as having a progressive approach to regulation. Aligned with this, Leef (2015) and Ward (1992) claim that since 1991, there has been strong political and public support for the relaxation of regulations by the FDA in the United States.

Coffey (2008) and the authors mentioned above believe that over-regulation stifles new pharmaceutical product innovation and also delays the manufacturing of, and public access to, much-needed medical products. They call for a balance between the need for strong scientifically based regulatory policies and the need to understand the complex relationship between the social and economic requirements of a sustainable pharmaceutical industry. This accentuates the adhocracy and market cultural characteristics of the United States region and ultimately highlights that, on the basis of literature, there is a noteworthy difference between the cultural orientations in Japan, Europe and the United States, with reference to regulatory concerns.

4.3.3 Stakeholders and division of labour

This section of the comparative study explores the pharmaceutical manufacturing stakeholders of the ICH tripartite and the division of labour among those stakeholders. Literature (Mankar, Gholap, Zende and Dighe, 2014, Management Sciences for Health, 2012 and Coffey, 2008) suggests that stakeholders and the division of labour are closely interlinked since various functions are performed by different stakeholders. These two highly related concepts are presented in a single section in this Activity Theory comparative study. The stakeholders that are examined in this section are NRAs, governments, sellers and buyers in the pharmaceutical industry.

Earlier in this chapter, it was emphasised that the ICH was a stakeholder of all three pharmaceutical industries because the role of the ICH was to promote harmonisation between the industries. The function performed by the ICH, therefore, denotes that an element of clan culture is necessary to promote and ensure effective quality management in the global pharmaceutical industry. The ICH supports NRAs in all three geographical regions and NRAs, in turn, serve as the WHO's vehicle for the regulation of pharmaceutical production in organisations. The activities of the NRAs vary between the three geographical regions in terms of the scope of their authority and the implementation of their requirements. Chakote (2016) and Rägo and Santoso (2008), however, point out that the principle regulatory roles of the NRAs in all three regions are the same. These are the issuing of market authorisations for individual products, the inspection and surveillance of pharmaceutical manufacturers, the monitoring and control of the quality of pharmaceuticals already on the market, control of the promotion and advertising of pharmaceuticals, issuing of independent information about pharmaceuticals to professionals and the public and monitoring of the safety of marketed pharmaceuticals. Thus, it can be deduced that the duties performed by NRAs in each of the regions are similar and that hierarchical culture is necessary to support pharmaceutical manufacturing in all three regions.

Significant distinctions between the influences of stakeholders on the ICH geographical regions only begin to emerge when the effect of government on

pharmaceutical production in these regions is examined. Government plays an important role in policy development and assists with the regulation in pharmaceutical industries to varying degrees in these three regions.

According to Ribbink (2016) and Umumera (2011), the government is the most influential stakeholder of the pharmaceutical industry in Japan. From post-World War II until the 1990s, the Japanese government fiercely protected the pharmaceutical industry, as it had been completely devastated in the war; however, the inadvertent consequence of this was the stagnated growth of the industry (Umumera 2013). When this was realised in the early 1990s, the Japanese government began to harmonize with other countries, and in June 2013, the Japanese government initiated a Japan Revitalisation Strategy aimed at achieving international competitiveness in the healthcare and medical sector, including the pharmaceutical industry. Ribbink (2016) states that, through the MHLW, the Japanese government reviewed the regulatory processes with the objective of enhancing efficiency and productivity. Thus, Japan is seen as following the trend that was set in the United States. Japan established an agency called the Agency for Medical Research and Development (AMED) in 2015 to promote OpEx in the pharmaceutical industry (Ribbink 2016). It can be presumed that the reason for the move away from the previous hierarchical approach on the part of Japan was because of a realisation that exclusive hierarchy does not promote OpEx.

From a European perspective, there is very limited empirical evidence to support an argument that there is any benefit to direct government involvement in pharmaceutical production (Ball 2011; Bennett, Quick and Velásquez 1997), beyond establishing a stable economic and political environment. Some European governments, like France and Italy, have set objectives to establish state managed production operations for pharmaceutical products. However, due to the complexity involved in pharmaceutical production, these objectives are not realizable. Thus, a trend in Europe is that governments work in close collaboration with NRAs, which is perceived by this study to be an inclination towards clan culture.

Coffey (2008) asserts that in comparison to other governments, the United States government exerts the least amount of influence on its pharmaceutical industry. The rationale for this is that these functions are already performed by the FDA in the United States. The FDA is the most internationally recognised NRA and is described as a science-based, comprehensively established and robust agency (Courtney, Bond and Maher 2014; Coffey 2008). It is engaged in multiple efforts to ensure global health security and protect public health both in the United States and abroad. The United States government passes legislation which is then regulated by the FDA. However, in addition to the regulatory role, more than any other global NRA, the FDA actively provides very detailed and comprehensive guidance in order to actively support manufacturing in the pharmaceutical industry (United States Food and Drug Administration 2018b; Wiss 2015; Simon, Pataki, Marosi, Meemken, Hungerbühler, Baiker, Tummala, Glennon, Steele, Kramer, Rydzak, Chen, Morris, Kjell, Singh, Gani, Gernaey, Louhi-Kultanen, Oreilly, Sandler, Antikainen, Yliruusi, Frohberg, Ulrich, Braatz, Leyssens, Von Stosch, Oliveira, Wu, Khan, Ogrady, Pandey, Westra, Delle-Case, Pape, Angelosante, Maret, Steiger, Lenner, Abbou-Oucherif, Nagy, Litster, Kamaraju, and Chiu 2015; Courtney, Bond and Maher 2014, Hu, Scherngell, Man and Wang 2013; Coffey 2008). An example of such guidance is Process Analytical Technology (PAT) which is a risk-based tool to assure quality, promote innovation and assist pharmaceutical manufacturers in achieving operationally excellent status during pharmaceutical production. The conclusion derived from the evaluation of literature is that the role of the government in the United States pharmaceutical industry is overshadowed by the role of the FDA and that the government has, therefore, adopted an open, flexible stance to pharmaceutical manufacturing. The government supports the FDA with legislation; however, the FDA assumes the more proactive role and performs actions to assure the safety of pharmaceutical consumers and to promote OpEx within United States pharmaceutical manufacturers as a whole. The underpinning culture is, therefore, adhocracy and market driven.

Sellers and buyers do not have equal influence in the pharmaceutical industry. Whiteside (2016), Umemura (2013), Friedman (2012) and Coffey (2008) contend that, for the most part, pharmaceutical suppliers generally offer very widely available chemical commodities and thus have little power since commodities are available from numerous sources. This moderates the price of supplies. A distinction noted in Japanese supplier relationships was that prior to the 1990s, a typical feature of the Japanese pharmaceutical industry was the presence of "*keiretsu"* relationships. Keiretsu is characterised by commitment and a long-standing loyal partnership (Umemura 2013). This simultaneously restricted the development of the pharmaceutical manufacturing sector of the industry since a feature of keiretsu is the restriction of modernism and innovation. Post-harmonisation in the 1990s, these relationships began to unravel, and the Japanese pharmaceutical industry began to resemble the European and United States pharmaceutical industries. This study perceives this to be a move away from an unpinning hierarchical culture in Japan, towards a more market-driven culture.

Buyers of pharmaceutical products in the ICH regions have a more significant impact on the activity of pharmaceutical production in general. In all three regions, patients are the final consumers of pharmaceutical products; however, the primary buyer of the products is the medical fraternity or the government in the ICH regions (Courtney, Bond and Maher 2014; Ball 2011; Coffey 2008; Umemura 2008) since patients need the medical fraternity to decide on the most appropriate pharmaceutical product for them. Sato (2016) and Umemura (2011) believe that Japan's culturally distinct approach to medical therapy affected pharmaceutical manufacturing and was especially pronounced from 1960 to 1970. Medical doctors were unwilling to inform cancer patients of their illness because of the belief that receiving a cancer diagnosis was a death sentence and was unwelcome. Thus, doctors prescribed cancer medication with the least side effects instead, to prevent patients from discovering that they had a near-fatal disease. This practice only changed at the beginning of the 21st century. Umemura (2011) argues that innovation and growth in the Japanese pharmaceutical industry were stagnated as a result of this practice, due to the modest demand for pharmaceutical products. This study assumes that this

conservative medical culture is another form of the entrenched hierarchical culture that affected OpEx in the Japanese pharmaceutical industry.

In Europe, national healthcare systems are the primary buyers of pharmaceutical products (Friedli and Bellm 2013a; Gronauer, Friedli and Goetzfried 2010). Furthermore, European nations prize solidarity and public health (Mossialos, Mrazek and Walley 2004) and thus an inclination observed in this ICH region is a unified approach towards the provision of widespread access to medical services and pharmaceutical therapies. In European countries, a pharmaceutical product must be deemed cost effective by a national committee before it can be made available for prescription (European Medicines Agency 2016; Hassali, Alrasheedy, McLachlan, Nguyan, AL-Tamimi, Ibrahim and Aljadhey 2013). Therefore, beneficial price competition is difficult to achieve because of the underlying unified approach to satisfy buyers. This is in stark contrast to the United States where literature sources (Markarian 2017; Shanley 2017d; Seller and Davis 2013) indicate that organisations use quality management (including traditionally recognized Japanese practices such as Hoskin Kanri) to gain a competitive edge over other organisations and to secure buyers. The primary buyers in the United States region are the United States government and medical insurance schemes. The priorities of United States pharmaceutical producers are set by market demand from the buyers (Whiteside 2016; Mossialos, Mrazek and Walley 2004) and an underlying market-driven culture is foregrounded in this region. Market priorities then drive innovation (Shanley 2017d) in United States organisations. This study, therefore, deduces that the United States pharmaceutical manufacturers are more competitive and innovative than manufacturers in the other two regions.

4.3.4 Tensions

The Activity Theory framework allows this study to illuminate the areas in the global pharmaceutical industry where transformation is required (Engeström 2014). The resolution of the tensions showcased by this study signifies the broad areas where improvement toward OpEx in the ICH regions took place and thereby provides this study with guidance when developing a conceptual OpEx

Model for South Africa. Awareness of the underlying culture which directs behaviour is foregrounded by the examination of tensions. This provides an organisation with a vantage point to evaluate and tailor their quality management strategy. In essence, this comparative study demonstrates that the measurement of culture should be an essential part of any quality strategy.

Research finds that, in spite of the absence of literature on the specific quality tools that are used during pharmaceutical manufacturing in Japan, the Japanese are internationally recognised for being experts in quality management (Corriero 2018). Notwithstanding this status, the Japanese pharmaceutical industry never achieved the same global status and level of OpEx as Europe or the United States, even though they started from being a nonentity in 1945 to catching up with the rest of the world by the 1970s. Japan failed to take advantage of their potential to be global leaders in pharmaceutical production. It can be surmised that this was due in part to contradictions between the reasons for GMP, the restrictive government regulations and the Japanese medical culture. A bureaucratic regulatory culture overshadowed the quality management efforts which would typically elevate performance levels in pharmaceutical manufacturing. Significantly, the secretive Japanese medical culture also played a role which undermined the growth of the industry.

Literature illustrates that the overruling culture in Japan is hierarchical in nature, which is consistent with the findings in Chapter Two of this study, where Williams (2008) described the national quality award in Japan as highly prescriptive in nature. This study deduces that the realisation that change was required in the pharmaceutical industry occurred in the early 1990s, therefore, initiatives to promote OpEx took place since then. International pressure led to the relaxation of regulation in the industry and openness to harmonisation. While the initiatives have been successful, the contradictions associated with culture highlighted by this comparative study had a negative impact on the success of OpEx in the Japanese pharmaceutical industry.

In Europe, a region-specific emphasis on strategy and people was observed. Good Manufacturing Practice lends itself to an underlying hierarchical cultural

approach in every pharmaceutical manufacturer. However, in addition to a primary hierarchical culture, a movement towards a balance between hierarchy and clan culture was noted in the literature on Europe. Literature (Ball 2011; Bennett, Quick and Velásquez 1997) further indicates that there is less direct government involvement in the pharmaceutical industry in the European region than in Japan. European pharmaceutical manufacturers collectively work towards a unified approach to regulation in collaboration with the European Medicines Regulatory Network, and towards meeting the customer needs in collaboration with European NRAs. Another indicator of this is the EFQM quality award which places more emphasis on the involvement of people than the quality awards in the other two regions. Thus, clan culture firmly underpins efforts toward OpEx in pharmaceutical manufacturing in the European region. Within the European region itself, no tensions were noted within quality management tools, regulations, stakeholders and division of labour. However, dichotomies emerged when comparing Europe to Japan and Europe to the United States.

The United States is recognised as the most successful global pharmaceutical industry regarding global sales and market share (European Federation of Pharmaceutical Industries and Associations 2017). When comparing the United States to the Japanese and European regions in general, it was found that the United States adopted a meaningfully more aggressively competitive approach to pharmaceutical manufacturing. Significantly, the quality management tools promoted by the FDA, for example, PAT has a non-prescriptive threefold emphasis on ‘strategy’, ‘people’ and ‘operations’. This balanced approach is aligned with the United States quality award (MBNQA) criteria which measure organisational performance and customer focus in all organisational operations and activities. Within the United States pharmaceutical industry, tensions were observed within the regulatory element of Activity Theory. From the 1990s there has been strong political and public support towards the relaxation of regulation by the FDA. Although such relaxation has not taken place (Courtney 2018), this points to an underlying culture that is more flexible than a rigid hierarchical culture. The most significant tension in the United States is between regulation and an open market. Innovation and market-driven traits are valued in the United States.

This study highlights the most valued traits which direct the behaviour towards OpEx in each region. Collectively, valued traits constitute culture and thus culture influences the progression of OpEx in each of these regions. In general, Japan values order, procedures and instructions. Europe values being part of a team and in the United States, innovation and continuous improvement is valued as well as being recognized in the market. The deduction of this comparative study is that all these values are required for sustainable quality management that leads to OpEx. Thus, the OCAI is a tool to measure the proportion of each culture type in an organisation.

4.4 Chapter summary

This chapter draws attention to the variety and balance of OCAI culture types that support continual improvement and development in the pharmaceutical industry. The OCAI cultural research lens enables the scrutiny of the underpinning culture in each geographical region and highlights tensions that emerge during each region's transition to improved OpEx levels. In alignment with the ultimate objective of this study, which is to develop a conceptual OpEx Model this chapter examines the role of the four culture types in pharmaceutical manufacturing in the ICH regions. The findings of this chapter are strongly associated with the findings of Chapter Two, which is that culture directs the behaviour of people. Culture is an unseen control mechanism for the daily routines and execution of operational tasks, and accordingly, culture must not be overlooked during the management of quality. The amalgamation of the findings of all previous chapters with this chapter, leads this study to deduce that the adoption of Quality Management Practices will enable an organisation to improve itself in all dimensions continuously and that the underlying Quality Culture which supports Quality Management Practices is also a vital independent variable on which OpEx rests.

The next chapter outlines the research plan to be followed by this study, in analysing the current status of South African pharmaceutical manufacturing organisations and thereafter in developing a conceptual Model of Quality

Management Practices for the use of South African pharmaceutical organisations.

CHAPTER FIVE
RESEARCH DESIGN AND METHODOLOGY

'A bad system will beat a good person every time.'

- Dr William Edward Deming

This chapter presents the methodological rationale for the mixed method research design adopted in this study. The preceding chapters presented a broad scope theoretical examination of the research environment and highlighted the importance of culture. On the foundation of the aforementioned theory, this chapter initiates the empirical component of this study, through the provision of the research design which is focused on South Africa. It reviews the pilot study that was conducted and introduces the main study. The sampling method is discussed, and the plans to analyse quantitative and qualitative data are described. Thereafter this chapter outlines the research considerations around validity and reliability and the ethical guidelines used during this study.

Essentially, this chapter five is the heart of this thesis since it synthesises the conceptual framework formulated through the review of literature in the preceding chapters to meet the final two research objectives of this study.

5.1 Background to research methodology

Dottin (2001) argues that a conceptual framework may act as the stimulation for a study. An extensive literature search gave rise to the conceptual framework which stimulated this study and is depicted in Figure 5.1. This conceptual framework is the theoretical structure of assumptions and principles, derived from literature, and illustrates concepts that comprise the broad concept of culture and its impact on OpEx.

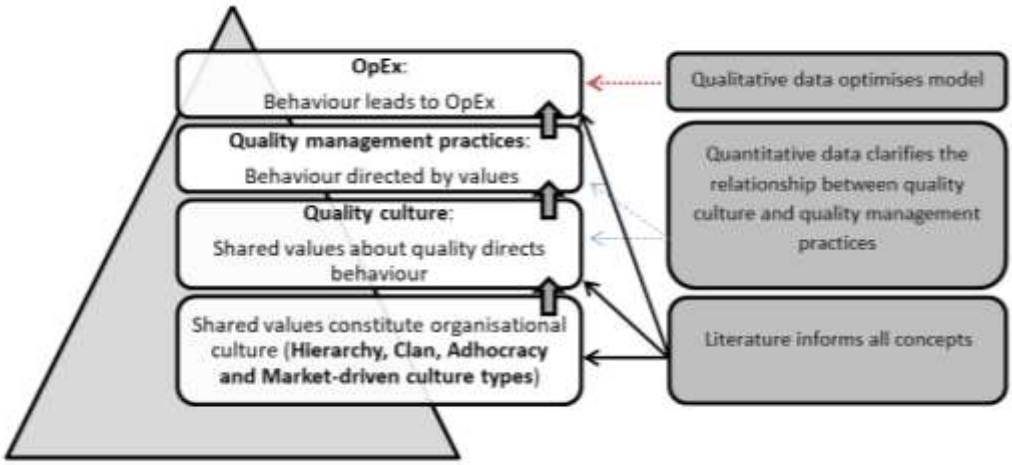


Figure 5.1: Conceptual framework (Developed by the Researcher)

Certain empirical studies (Valmohammadi and Roshanzamir 2015; Friedli *et al.* 2013; Friedli and Goetzfried 2010) have portrayed Quality Management Practices as a precursor to OpEx in pharmaceutical organisations. These studies provided the perspective from which this study sets out, to solve the research problem, which is to try to reduce the disproportionate gap between the two-tiered South African healthcare system by assisting pharmaceutical manufacturers to elevate their levels of operational performance. Chapter One of this study notes that a dearth of knowledge on the impact of Quality Culture has hindered South African pharmaceutical manufacturing organisations from selecting the most suitable Quality Management Practices in OpEx strategies. This prompted a detailed literature examination which gave rise to the conceptual framework above. This framework provides the scaffold of the research design to develop a conceptual Model to address the research problem.

To solve the research problem, the framework relies on two phases of data collection and analysis, namely quantitative and qualitative phases which are discussed in the proceeding sections of this chapter. Phase one involves a quantitative survey. The findings of data analysis obtained from phase one combined with findings derived from the associated literature enable model development. Following this, phase two entails qualitative data collection and data analysis to optimise the conceptual OpEx Model. The next section of this chapter contextualises the research approach regarding general research paradigms before data collection is discussed in greater detail.

5.2 Research philosophies and worldviews

Research is a systematic and methodical process of enquiry and investigation which increases the current state of knowledge (Mouton 2011; Collis and Hussey 2009) and is used to solve problems. The intention of research is thus always to address a gap in theory. Importantly, Mouton (2011) highlights that the methodological approach adopted in a research study must adequately enable the closure of the gap. Therefore, current theory plays a role in directing the research design chosen for a particular study. Aligned with Mouton (2011), Cresswell (2014) argues that to do this, a Researcher must carefully consider each of the three central methodological approaches when selecting the research approach to expand upon existing theory for a particular study. The three central research approaches are qualitative, quantitative and mixed methods, as illustrated in Figure 5.2.

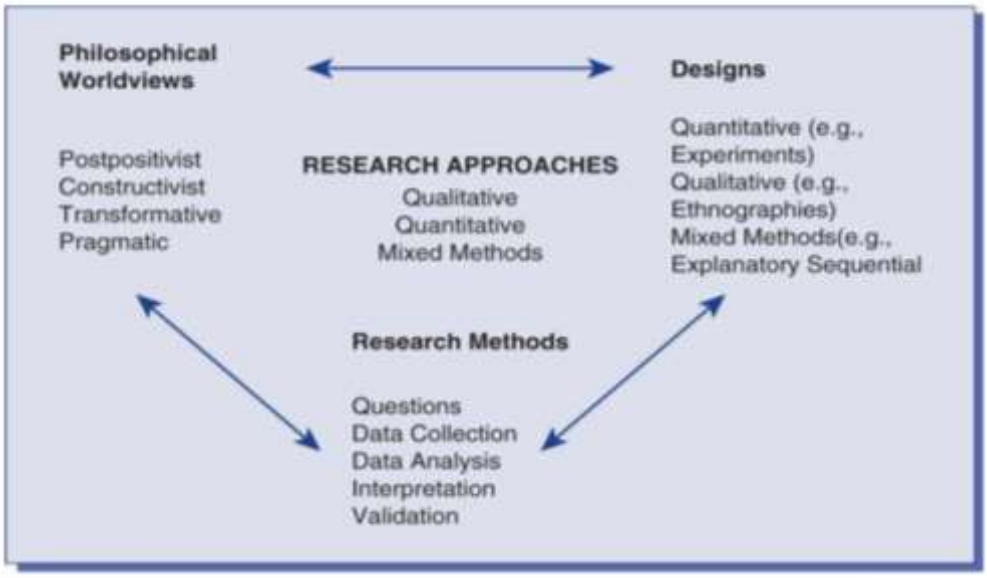


Figure 5.2 A framework for research – The interconnection of worldviews, design and research methods **(Cresswell, 2014)**

Cresswell (2014) elucidates that a "worldview", also known as a paradigm, is a set of basic beliefs held by the Researcher that guides the Researcher's actions. It is the general philosophical orientation of the Researcher. With reference to Figure 5.2, he argues that post-positivist research lends itself to measuring or quantifying data and is also commonly referred to as scientific or empirical

research. Problems studied by post-positivists reflect the need to identify and assess 'causes' that influence outcomes, for example, in experiments. Cresswell (2014) and Hesse-Biber (2010) argue that post-positivist research has the tendency to be reductionistic and deductive.

On the other hand, Cresswell (2014) and Mouton (2011) conclude that constructivists, also known as interpretivists, believe that differences in the social world are subjective and reality is constructed in the mind of an individual based on the experience of that individual. Knowledge gathering and truth are always partial. This highlights the limitations associated with reductionism, in light of the goal of constructivism, which is to rely on participants' views of a situation to construct meaning and solve a problem. This worldview lends itself to describing or interpreting the qualities of data, and it is inductive.

To comprehensively examine the South African pharmaceutical industry and thereafter develop a conceptual Model of Quality Management Practices for industry to use, neither a post-positive nor constructivist approach as standalone approaches is sufficient. This study, therefore, requires a mixed methods approach with features that are typically associated with pragmatism. Pragmatism is not committed to any one system of philosophy or reality and applies to mixed methods research (Cresswell 2014). When using a pragmatic approach, Researchers liberally draw from both qualitative and quantitative assumptions when they engage in their research to solve the problem. According to Bazeley (2017), mixed methods enrich the understanding of a situation through confirmation of conclusions, extension of knowledge or the initiation of new ways of thinking about a subject of research. Mixed methods are, inherently neither more nor less valid than specific qualitative or quantitative approaches. The validity of any research method stems from the appropriateness, the thoroughness and the effectiveness with which that particular method is applied, and the care given to the thoughtful weighing of evidence rather than from the application of a particular set of rules or adherence to an established tradition.
The reason for using mixed methods must, therefore, be very clear. Plano Clark *et al.* (2008) identify four major models of mixed methods research designs, each with a different purpose, namely triangulation, descriptive explanatory,

exploratory, and embedded design. An illustrative depiction of these designs is presented in Figure 5.3.

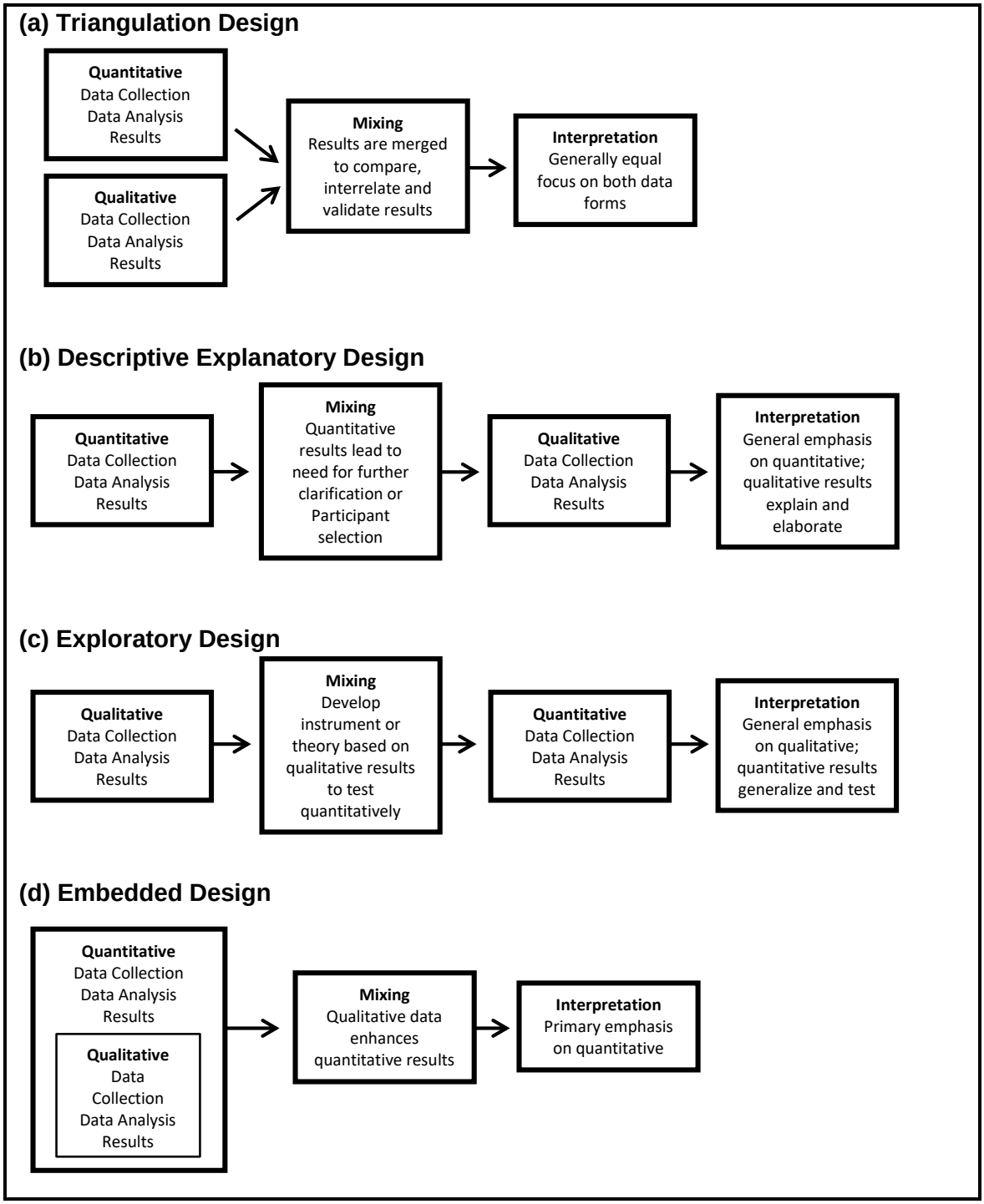


Figure 5.3 Four models of mixed method research design (**Source:** Adapted from Plano Clark *et al.* 2008

Guided by the illustration in Figure 5.3, this study can be described as an embedded design. Statistical results must be obtained from the analysis of quantitative data to provide a dais for subsequent and more in-depth qualitative

exploration of a smaller purposefully selected sample of individuals. Therefore, this study can be described as a two-phase sequential embedded mixed methods study where quantitative analysis first explores the relationship between Quality Culture and Quality Management Practices in the initial phase. The result of this analysis provides research with a view of the current status of OpEx in South African pharmaceutical organisations. This initiates the second phase wherein qualitative interviews are used to probe significant quantitative results by exploring aspects of the effect of Organisational culture on Quality Management Practices that translate into OpEx.

5.3 Methodological paradigm of the study

An empirical component must be designed specifically to meet the fourth and fifth objectives of this study, which are:

- Conduct a focused study on Quality Management Practices, based on data collected from selected manufacturers of Category A medicines in the pharmaceutical industry in South Africa.
- Develop a Model of Quality Management Practices supported by Quality Culture for Category A manufacturers in the South African Pharmaceutical Industry.

This research found that Organisational Culture has an impact on OpEx in organisations (Valmohammadi and Roshanzamir 2015, Friedli *et al.* 2013, Friedli and Goetzfried 2010; Cameron and Quinn, 2008) and that there is a direct association between Quality Culture and quality outcomes (Keeling, Rutten and Telpis, 2017; Hussain, 2015; Malhi, 2013). However, further theoretical interrogation and empirical evidence are required to explore this from a South African perspective. An appropriate multifaceted research design must, therefore, be developed in order to do so.

Bazeley (2017), Creswell (2014), Babbie (2010), Hesse-Biber (2010), and Plano Clark *et al.* (2008) promote the mixed methods research design as one that is ideally suited to address a research problem with a complex nature. A significant advantage of the mixed method approach is that this design is capable of being

both deductive and inductive. Cresswell (2014) points out that by combining both deductive and inductive processes, the Researcher tends to base knowledge claims on pragmatic grounds. A noteworthy criticism levied against the mixed methods research approach, is the perceived lack of concreteness and the final authority of a specific approach (Doherty-Bigara, 2014) which results in an unsettled characterisation of a mixed methods study which may be regarded as a weakness. A robust design such as the one presented in Figure 5.4 is capable of overcoming this weakness. This graphic illustration depicts the research process followed by this study and includes both inductive and deductive processes.

The Research Process

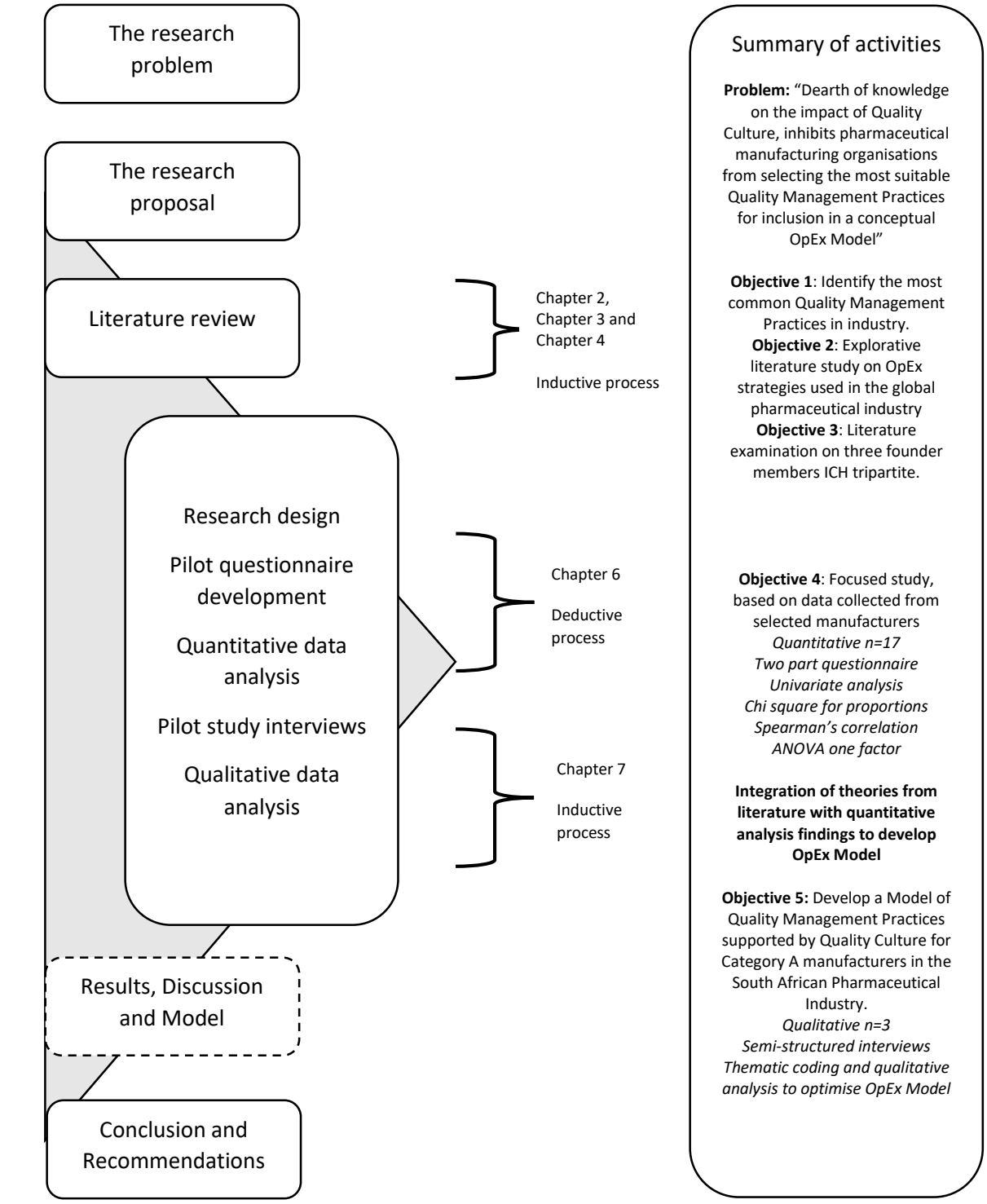


Figure 5.4 The research process (Developed by the Researcher)

Figure 5.4 portrays the two empirical phases (deductive quantitative and inductive qualitative) in a sequential embedded research design to develop a conceptual OpEx Model for South African pharmaceutical manufacturers. During the first empirical phase, numerical data is collected from manufacturers using a two-part research instrument. The first part of this quantitative instrument (questionnaire) obtains an overview of the South African pharmaceutical industry with regard to Quality Management Practices and Quality Culture and Climate associated with those practices. The second part of the questionnaire obtains information from pharmaceutical manufacturers about the underpinning OCAI culture in the South African pharmaceutical industry. Triangulation of the data obtained by both parts of the research instrument provides a holistic view of the current landscape of the South African pharmaceutical industry.

5.4 Data collection

When focusing on the nature of the embedded design which was selected for this study, it was noted that a very important feature that characterises such a design, namely that the two data sets of such a study are collected for two distinctly different reasons. With an embedded research design the successful collection and analysis of the second data set rest upon the successful collection and analysis of the first data set (Hesse-Biber, 2010). Accordingly, in this study, the success of the qualitative OpEx Model development phase depends on the successful completion of the quantitative phase. Therefore, special care was taken when planning the collection of data to ensure that adequate and suitable data was appropriately collected in both of the sequential stages of this embedded design study.

5.4.1 Quantitative data collection

The target population of this study is all Category A pharmaceutical manufacturers in South Africa. A list of all the manufacturers was obtained from the MCC before data collection commenced, and it was noted that only 58 organisations appeared on this list. After telephonically contacting 56 of the organisations, only 30 were confirmed to be current manufacturers of pharmaceutical products in South Africa. Twenty-six either did not have a current

licence or they were not manufacturing any longer. Two organisations could not be contacted as contact details provided by MCC were out-dated (telephone numbers invalid). An internet search did not produce any new information indicating that the organisations still existed. Thus, the target population consisted of 30 organisations.

When a target population is less than 100 units, a census sample must be attempted (Singh and Naidoo, 2012). In general, quantitative research allows generalisations to be made (Mouton, 2011), thus it is appropriate for a questionnaire to be sent to each member of the target population, to examine the current Quality Management Practices in South Africa. Furthermore, to obtain a representative view of the overall Quality Culture in each organisation, four specific roles (two management and two operators) in each pharmaceutical manufacturing organisation were requested to complete the questionnaire in order for the Researcher to profile the organisation as a whole.

5.4.2 Qualitative data collection

The aim of the qualitative phase, on the other hand, is to gain a contextual understanding of the impact of culture on pharmaceutical organisations in South Africa. In respect of this, guidance was derived from Mouton (2011) who argued that conceptual studies and model building could be empirical in nature when existing data is used. A phenomenological and situational view was thus sought from participants to interrogate quantitative findings. Participants were from selected organisations based in the three most geographically important regions in South Africa. Cape Town, Johannesburg and Durban are the top three South African cities with the most Category A pharmaceutical manufacturers. Thus, nonprobability purposive sampling is the sampling technique used in the qualitative phase of this research. With nonprobability purposive sampling, the Researcher determines the types of elements needed in the sample (Hesser-Biber, 2010) and purposively selects them based on these criteria. The criteria in this study are being geographically representative and a Category A pharmaceutical manufacturer.

In the research process, data analysis takes place after data collection (Babie 2010). However, prior to a discussion on the main study data analysis methods, a discussion of the pilot study is presented in this chapter. This is done to clarify the aim of data analysis and thereby justify the data analysis methods (presented in section 5.6) used by this study.

5.5 The pilot study

The pilot or 'feasibility' study of this research process is described by Yin (2014) as a small scale preliminary study performed on one pharmaceutical manufacturer organisation to reveal risks, mistakes or flaws in the design of the research instrument, such as ambiguous questions (Yin 2014). Cooper and Schindler (2014) agree, adding that the purpose is to highlight unknown factors or overlooked assumptions that might potentially have a negative impact on the study and then to improve the research instrument design prior to deployment in a full-scale main study.

The ensuing section discusses the pilot study under five headings as follows:

- The pilot study organisation is described, and justifications for the selection of pilot organisation are provided.
- The structure of the quantitative pilot study instrument is outlined, and the aim of the instrument is presented.
- A description of the execution of the quantitative pilot study is provided, and changes that were required to be made for the main study instrument are highlighted.
- The development of the qualitative pilot study instrument is described with aims of the qualitative pilot study.
- A description of the execution of the qualitative pilot study is presented, and changes that were required to be made for the main study instrument are highlighted.

It is worth noting that it was not possible to start the qualitative pilot study before the main quantitative study was complete. The findings of data analysis from the main quantitative study were used to develop the qualitative pilot study instrument

in this embedded research design, therefore, quantitative data analysis needed to be complete. Essentially, the quantitative findings directed the development of the qualitative pilot study instrument.

5.5.1 Pilot Study Organisation

Rahman (2015) and Peat, Mellis and Williams (2002) advise that pilot study participants be excluded from the target population of the main study. The rationale for this is that the objective of a pilot study is to determine if the research instrument can be improved before the final data collection. Thus, if there is a change or an improvement to the instrument after the pilot study, it may be assumed that the quality of the data obtained in the main study is different to that obtained in the pilot. Combining pilot study data and main study data can thus have a negative impact on the outcome of data analysis, and should, therefore, not take place.

A single pilot organisation was purposefully selected based on critical characteristics that allowed it to represent the target population as closely as possible, in order for relevant testing of the research instrument to take place. The pilot organisation does not produce final Category A products; however, the organisation produces bulk form pharmaceuticals for export purposes in accordance with GMP. The sampling technique used to select the pilot study organisation was thus convenient non-probability sampling based on geographic location and proximity to the Researcher. Prior to the commencement of the pilot study, the Researcher obtained consent from pilot participants.

5.5.2 Structure of the Pilot Study Questionnaire

The design process of the quantitative component (two-part questionnaire) revolves specifically around ensuring that the instrument would be capable of facilitating a focused study of the Quality Management Practices of Category A medicine manufacturers in South Africa. Part one of the pilot study questionnaire consists of four sections which each serve a different purpose. The first section (Section A) collects demographic information on the Participant. The next three sections (Section B, C and D) form the main part of the questionnaire. These

sections consist of research variables (questions) which measure the participants' perceptions on a seven-point Lickert scale and were developed from the analysis of literature in Chapter Two and Three. Section B consists of 10 variables which explore participant perception on GMP mandated Quality Management Practices in their organisation. Section C consists of 10 variables which explore Quality Culture, and section D has 8 variables that explore Quality Climate within the organisation.

Part one of the questionnaire is designed so that individual variables in each of the three sections (B, C and D) could be reconstructed. Once reconstructed, the 'new' group of reconstructed variables will be able to measure dimensions of OpEx as listed in Chapter Two, namely Leadership, Strategy, Systems Approach, Customer Focus, Continual Improvement, Employee Empowerment, Fact-based Management, Supplier partnership, Training and Agility. A graphic depiction of the reconstruction process is shown in Annexure 5A. The last three variables in Section D of the questionnaire are not used in the reconstructed design. These three questions are aimed at understanding how open the organisation would be to innovation as a result of an OpEx strategy.

Part two of the pilot study questionnaire consists of 6 questions seeking participant perceptions of the OCAI culture traits of their organisation. This questionnaire is an adaption of an open source validated standard research instrument (Heritage, Pollock and Roberts, 2014) which was developed to assess the current organisational culture based on the competing values framework presented in Chapter Two. The OCAI designed for this study consists of six variables, each composed of four alternative descriptions that match the four culture types. A score must be assigned to each of those alternative descriptions by research participants. The total combined score should be 100 points per variable. By dividing the 100 points among the four descriptions (culture types) the research participants are able to characterise their organisations by identifying the blend of culture that currently exists in the organisation, at the same time that part one of the questionnaire is completed.

In summary, this two-part pilot study questionnaire is designed to enable this study to achieve four aims, namely:

- Explore the relationship between Quality Management Practices and Quality Culture in the South African pharmaceutical industry (part one);
- Measure the current OpEx level in the South African pharmaceutical industry across the dimension represented by the reconstructed questionnaire (part one);
- Establish an OCAI culture types profile for the South African pharmaceutical industry (part two) and
- Determine if there is a relationship between OCAI culture types and the dimensions of OpEx (triangulation of data obtained from part one and part two).

5.5.3 Execution and Refinement of the Pilot Study Questionnaire

From June 2016 to January 2017 quantitative pilot data was collected with the two-part instrument mentioned and then analysed. Both parts of the questionnaire were completed by four personnel members in management positions and six personnel members in production operator positions at the pilot organisation.

Analysis of part one of the quantitative pilot study highlighted that research variable OC2 was not well understood by pilot study participants. The Cronbach Alpha coefficient verifies the internal reliability of data and only a reliability coefficient of 0.70 or higher is acceptable according to Tavakol and Dennick (2011). A reliability coefficient lower than 0.70 is an indicator that a question might have been ambiguous or double-barrelled. When this research variable was re-examined by the Researcher, it was found that it was negatively worded and thus it was assumed that it was not consistently understood by all pilot participants. Furthermore, another significant oversight highlighted by the pilot study was that research variable OC5 did not have a Lickert scale, and therefore, could not be analysed with the rest of the data. The necessary refinements were made to part one, namely the wording for research variable OC2 was

restructured, and a Lickert scale was added to research variable OC5. There were no changes required to part two of the questionnaire.

5.5.4 Development of the Pilot Study Interview Questions

Similarly to the quantitative pilot study, specific research aims were identified. Directed by the research problem of this study, which is "A dearth of knowledge on the impact of Quality Culture inhibits South African pharmaceutical manufacturing organisations from selecting the most suitable Quality Management Practices for inclusion in a conceptual OpEx Model", five pilot aims were set for the qualitative component of this study. Each aim is intended to represent an important step in the research process that will ultimately lead this research to comprehend how Quality Culture influences behaviour and OpEx in South African pharmaceutical organisations.

The aims of the qualitative research in this study are:

- To determine if the Quality Management Practices (identified through the integration of the literature review and main study quantitative analysis) are appropriate and suitable for inclusion in the conceptual OpEx Model. Furthermore, to determine if there are any Quality Management Practices missing from the Model;
- To examine the impact of OCAI cultural traits on Quality Management Practices;
- To determine if the OpEx dimensions (achieved through Quality Management Practices and identified through the integration of literature review and main study quantitative analysis) are appropriate and suitable and to determine if any dimensions are missing from the Model;
- To examine the impact of OCAI cultural traits on OpEx dimensions and;
- To interrogate the high-level structure of the Model to ensure that it adequately communicates the intended information to the user.

The design of the qualitative phase of this study only took place in March 2018, after the analysis for the quantitative phase data of the main study was completed. The design revolves around ensuring that semi-structured interview

questions on the foundation of Quality Culture would successfully enable conceptual OpEx model development for Category A manufacturers in the South African Pharmaceutical Industry. Conclusions were drawn from the literature reviewed in Chapter Two, Three and Four, as well as from the results of the empirical analysis in Chapter Six, and a proposed conceptual OpEx Model was developed. Five semi-structured pilot interview questions were developed to interrogate whether the concepts that were included in the proposed Model are valid and to determine if this study had inadvertently overlooked anything.

5.5.5 Execution and Refinement of the Pilot Study Interview Questions

Two pilot interview participants were selected because they were in management roles in the pilot organisation (quality manager and production manager). Pilot interviews took place on the 12th of April 2018. In separate interviews both participants expressed satisfaction with the basic structure of the proposed Model. However, both pilot study participants highlighted Hoskin Kanri, Validation Management, Visual Management and Data Integrity Management as a significant shortcoming of the Model. They also emphasised the value of the alignment of the organisation's vision and strategy with quality and quality objectives. This led the Researcher to perform an additional literature search before the main study interview took place. This was included in the review of the literature presented in Chapter Three.

The pilot study participants provided insight on the flow and structure of the interview when the actual questions were put to the participants. They were then asked to indicate how they had interpreted the formulated questions. Consequently, the language structure of the three questions was changed to eliminate ambiguity and irrelevant terms were removed from the questions.

5.6 Main study research methods

The following section outlines the plan to analyse data in the main study in quantitative phase and thereafter in the qualitative phases of this study.

5.6.1 Main study quantitative data analysis

The aims of the quantitative analysis (mentioned in section 5.5.2) remained unchanged from the pilot to the main study even though individual variables were refined to improve the study. The activities that need to take place in the four phases of the quantitative analysis of this study are presented in the tables below. Table 5.1 to 5.4 are lists of all the statistical tools that were employed by this study in order to achieve the four above-mentioned quantitative aims. A description of each tool is also provided as well as the context in which each tool is used. SPSS software is used for statistical analysis.

Table 5.1: Statistical analysis to explore the relationship between Quality Management Practices and Quality Culture in the South African pharmaceutical industry (Developed by the Researcher)

Name of statistical analysis	**Purpose of statistical analysis**	**Specific study details**
Cronbach's Alpha	Cronbach's Alpha is used to calculate the internal reliability of data (Tavkol and Dennick, 2011)	Cronbach's Alpha test ensures that each construct of latent variables is internally reliable.
Descriptive statistics on each individual variable	Univariate analysis is the simplest form of analysing data and indicates the proportion of respondents for each of the options given on the Lickert scale (Mann and Lacke, 2010).	Univariate analysis of each variable in Section B, C and D, (which explored Quality Management Practices, Quality Culture and Quality Climate respectively) was done.
Inferential statistics	Chi-square test for proportions indicates if there is a statistically significant difference between the proportions of participants who agree or disagree with a particular research variable (Field, 2009)	Chi-square for proportions enable this study to make statistical deductions on the general perception of South African pharmaceutical organisations on the importance of Quality Management Practices, Quality Culture and Quality Climate
	Correlations coefficients determine the strength of the relationship between two variables (Field, 2009).	Spearman rank correlations are used to determine the strength of the relationship between Quality Management Practices,

		Quality Culture and Quality Climate. Bivariate Spearman Rho analysis is used to determine the strength of the relationship between each individual research variable and every other variable.
	Linear regression analysis is a class of statistical tests that resides within ANOVA. This particular test can be used to develop a multivariate statistical model that explains the relationship between a dependent variable and two independent variables. (Normality test must be first done to confirm that ANOVA can be used) (Field 2009)	Linear regression analysis with ANOVA is used to develop a multivariate statistical model which indicates the strength of association when Quality Management Practices (dependent variable) and Quality Culture and Quality Climate (independent variables) are used.

Table 5.2: Statistical analysis to measure the current OpEx level in the South African pharmaceutical industry across the dimensions represented by reconstructed questionnaire (Developed by the Researcher)

Name of statistical analysis	**Purpose of statistical analysis**	**Specific study details**
Cronbach's Alpha	Cronbach's Alpha is used to calculate the internal reliability of data (Tavkol and Dennick, 2011).	Cronbach's Alpha test ensures that each reconstructed latent variable is internally reliable.
Inferential Statistics	Correlations coefficients determine the strength of the relationship between two variables (Field, 2009).	Results of bivariate Spearman Rho analysis are used to substantiate the reconstruction of latent variables to measure dimensions of OpEx.

Table 5.3: Statistical analysis to establish an OCAI culture type profile for the South African pharmaceutical industry (Developed by the Researcher).

Name of statistical analysis	**Purpose of statistical analysis**	**Specific study details**
Descriptive statistics of the overall OCAI profile	Spider charts are a graphical method of displaying multivariate data in the form of a two-dimensional chart	Spider charts provide this study with a graphic depiction of the overall perception of the pharmaceutical manufacturing organisations on the composition of OCAI culture types in the South African pharmaceutical industry (reported as four percentages). They can also be used to depict this information for each individual pharmaceutical manufacturing organisation
Inferential statistics	ANOVA is also used to compare the means of multiple groups (Field 2009). If the null hypothesis is rejected, a Tukey Kramer post hoc test is capable of doing a pairwise comparison to show which groups are significantly statistically different from one another.	In this part of the study, One-Factor ANOVA is used to determine if there is a significant statistical difference in the proportions of OCAI culture types in South African pharmaceutical organisations. If the null hypothesis is rejected, a Tukey Kramer post hoc test can be done to highlight significant statistical pairwise differences between the four OCAI culture type groups.

Table 5.4: Statistical analysis to determine if there is a relationship between OCAI culture types and the dimensions of OpEx (Developed by the Researcher).

Name of statistical analysis	Purpose of statistical analysis	Specific study details
Inferential statistics	Correlations coefficients determine the strength of the relationship between two variables (Field, 2009).	Triangulation of part one and part two of the questionnaire to identify the relationships that exist. Hypothesis testing with Spearman analysis to determine the strength of the relationship between each the dimensions of OpEx and OCAI culture traits.

5.6.2 Main study qualitative data analysis

The aim of the qualitative analysis (discussed in section 5.5.4) remains unchanged from the pilot to the main study; however, the language structure of the three questions was changed to improve the study.

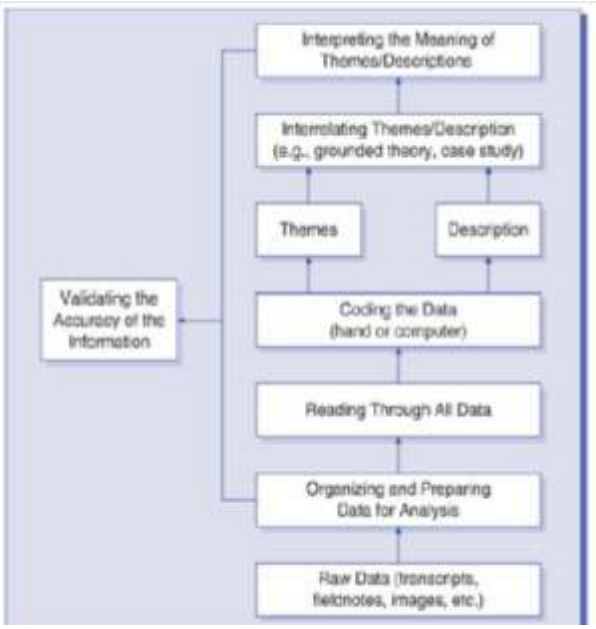


Figure 5.5 Steps in Qualitative Research (Cresswell, 2014)

The qualitative main study builds upon the findings of the main quantitative study. The activities that take place in the qualitative phase of the study are aligned with Cresswell's (2014) graphic representation of the steps in qualitative research, as displayed in Figure 5.5. It is also worth noting that Cresswell's (2014) view is consistent with the view of Bazeley (2017).

Bazeley (2017) offers seven basic steps for qualitative data analysis. First, prepare the data by transcribing and anonymising. Thereafter, inductively

explore the data by reading it and notice if any general themes emerge from the data. Third, manage the data by reducing, sorting and coding the data into relevant content related to the aim/s of the study. Fourth, describe the basic findings that are revealed by the data such as frequencies, descriptive statistics, higher order variables, conceptual codes and/or thematic categories. Fifth, undertake a comparative analysis to answer the research question and discern the deeper meaning of the data by identifying patterns. Sixth, investigate any patterns that have been uncovered. Finally, report the results with inferences and interpretations to ultimately solve the research problem.

Thematic analysis is the approach adopted by this study to transform data into valuable findings to solve the research problem. Bazeley (2013) asserts that code categories are central concepts in the thematic analysis as depicted in Figure 5.6. The code categories emerge from the preceding aims mentioned of qualitative research. From the code categories, the codes which are used to analyse the data are derived, and ultimately the relationships between the code categories give rise to themes that develop a new theory to solve the research problem.

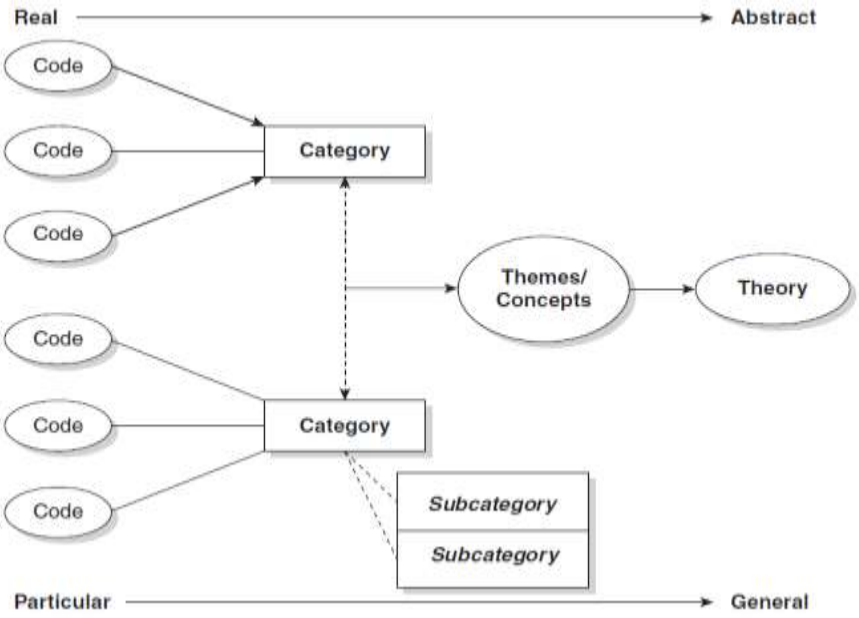


Figure 5.6: From codes to theory (Bazeley, 2013)

Thus, Table 5.5 presents the central code categories of this study. Some of the codes are derived from the pilot study, and other codes emerged during the main study. All the codes used for the main study data analysis in this study are captured in Table 5.5. Two codes were used in two categories as they fit in both categories (marked with a * below). A code category may be referred to as a code family or a concept family.

Table 5.5: Codes, Code Categories and Themes

Aim of Qualitative Research	Code Categories	Codes	Anticipated Themes
Structure of the conceptual OpEx Model	Structure of the Model (7 codes)	Broad outline of the Model is Good (new)* Model for Gap Analysis (new)* Org Vision-Culture-Strat-Mission KPI to Targets Resources to Results Multiple QMP/Dimensions Needed (new) Multiple Culture Types Needed	The conceptual OpEx Model is essentially the tool to operationalise this research study. Therefore, the appropriateness of the structure of the Model must be rigorously qualitatively interrogated. Qualitative data analysis is able to yield deeper, richer findings (Bazeley, 2017), than quantitative analysis, although the result of this analysis is not necessarily transferrable or generalizable. The relationship of all the code categories associated with the structure of the Model must be compared to another code category to uncover specific attributes associated with the South African pharmaceutical industry.
	Model is Adequate (6 codes)	Agrees with Dimensions Agrees with QMP Dimensions Adequate (new) QMP Adequate (new) Broad outline of Model Good (new)* Model for Gap Analysis (new)*	
	Model is Lacking (7 codes)	Disagrees with Dimensions Disagrees with QMP Dimension Missing QMP Missing Dimension Unnecessary (new) QMP Unnecessary (new) Model is Lacking	
Dimensions of OpEx	OpEx Dimensions (9 codes)	OpEx Dim 1 Strategy	

		OpEx Dim 2 Leadership OpEx Dim 3 Systems Approach OpEx Dim 4 Employee Empower OpEx Dim 5 Customer Focus OpEx Dim 6 Cont Improvement OpEx Dim 7 Fact-Based Manage OpEx Dim 8 Training and Agility OpEx Dim 9 Supplier Management	The relationship between the OpEx Dimensions code category and QMP for OpEx code category is explored to determine if the appropriate Quality Management Practices have been positioned in suitable dimensions in the model. The underpinning culture of each of the OpEx Dimensions and Quality Management Practices is explored.
Quality Management Practices	QMP for OpEx (15 codes)	CAPA Management Change Control Management Data Integrity Management Deviation Management Hoskin Kanri Maintenance Management Product Quality Review Management Recall Management Risk Management Self-Inspection SOP Management Training Validation Management Visual Management	
Culture	Culture (6 codes)	Hierarchy Clan Adhocracy Market Balance needed Culture supports OpEx	Culture is a central concept of this study, therefore, the relationships between the Culture code category and all other code categories (Structure of the Model, OpEx Dimensions and QMP for OpEx).

Bazeley (2017) argues that coding represents a form of data reduction. Furthermore, during the process of coding, it was common practice to make memos which link one or more codes to the higher level concept. During this research process, memos were used to facilitate the development of themes. This research describes the relationships between code categories and the association of these with research themes. Thereafter, this study moves beyond description of codes and themes as data becomes an interpretive model based on themes. ATLASti software was used for the qualitative analysis. Ultimately, awareness of the relationships between the qualitative themes provides this study with knowledge on the impact of Quality Culture, to facilitate the selection of the most suitable Quality Management Practices for inclusion in a conceptual OpEx Model for the South African pharmaceutical industry.

5.7 Validity, reliability and ethical considerations

Validity, reliability and due ethical consideration are widely regarded as cornerstones of good scientific research (Fendler 2016). The following section is an outline of the validity, reliability and ethical considerations of this study.

5.7.1 Validity and reliability

The concepts of ‘validity’ and ‘reliability’ of research data are concerned with the prevention of error in the data (Mouton, 2011). Hesse-Biber (2010) points out that the ‘correctness’ of one method or both methods in a mixed research design does not render the research valid or invalid since all methods produce results that are valid under certain circumstances and invalid under other circumstances. Validity and reliability are thus not inherent properties pertaining to a method, but pertain to the data and the conclusion reached by using that method in a particular context for a particular purpose. This foregrounds the necessity of adequately ensuring the quality of results in this embedded mixed method study. Duly, each part of this study design, as well as the interface of the two methods, is assessed in terms of validity and reliability and presented in the following sections.

5.7.1a Validity and reliability of the quantitative study

In a quantitative study, internal validity is affected by a causal relationship between research variables (Cresswell, 2014), for example, when not all the questions of the questionnaires are equally well understood. To ensure internal consistency of scales in part one of the research questionnaire of this study and integrity of results, the Cronbach's Alpha statistical technique was applied prior to the data being analysed. Cresswell (2014) states that this technique also confirms the reliability of an ordinal quantitative instrument.

Part two of this study's questionnaire is an adaptation of a standard open source research instrument which was previously validated by Heritage, Pollock and Roberts (2014). The content and structure of the research variables in the questionnaire were not changed except to reflect the South African pharmaceutical industry context; therefore, according to Mouton (2011), it is acceptable to regard it as internally valid (measurement validity).

The themes of three main data constructs (section B, C and D) of the research instrument came from literature; thus content validity was ensured. Furthermore, Bartlett (2014) is of the opinion that a pilot study imparts external validity on a study. Testing by means of a pilot study ensures that there is not a mismatch between research questions and the type of analysis used. External validity is also compromised if the sample is not representative of the population (Collis and Hussey 2009). This study notes that a census sample eliminates bias in the study design and allows a Researcher to draw the most accurate and thorough conclusions regarding the whole population; therefore, a census sample and a pilot study were identified as mechanisms for this study to ensure external validity. Furthermore, a significant feature particular to this embedded design is that certain findings of the quantitative phase of the study were validated by research participants (who are regarded as experts in the pharmaceutical industry) during the qualitative phase of the study.

5.7.1b Validity and reliability of the qualitative study

To ensure validity in a qualitative study, the Researcher needs to ask "*How might your results and conclusions be wrong*?" (Maxwell 2009), and then take the

necessary measures to ensure credibility of the results. With this goal in mind, and following transcription of interviews, the anonymised interview transcripts were returned to the three interview participants of the qualitative main study of this research, and the participants were asked to confirm the accuracy of the transcripts. This ensures the internal validity of the qualitative research results.

Identical to the quantitative phase, the pilot qualitative study imparts external validity as it ensures that there is not a mismatch between semi-structured interview questions and the type of analysis used to obtain results to solve the research problem (Bartlett 2014). Furthermore, the Researcher used data saturation as a technique during data collection to ensure external validity (Saunders, Sim, Kingstone, Baker, Waterfield, Bartlam, Burroughs and Jinks 2017). Equally important, the external validity was also insured by the Researcher evaluating the interview transcripts against an adaptation of Plummer's (2001) checklist of factors (see Annexure 5B). This allows the Researcher to safeguard against sources of bias that influence or contaminate research data. These sources are participant history, (for example, information about participant history that is overlooked and influences data), Researcher bias (for example, the presentation or body language of the Researcher that influences data) and interaction (for example, the social setting where interviews take place). All these factors are considered in terms of their potential to influence the data obtained. Finally, following data analysis, the findings of data analysis are peer-reviewed by a colleague of the Researcher (fellow PhD student) to confirm that the outcome of data analysis is valid.

5.7.2 Ethical considerations

Ethical clearance to perform this research was obtained from Durban University of Technology (DUT), and the Researcher ensured that DUT's Research Ethics Policy and Guidelines were strictly adhered to as per PG 2a Research Ethics Checklist. These are consistent with the ethical considerations advocated by Dicicco-Bloom and Crabtree (2006) which include:

- The Researcher should be vigilant about factors that indicate that the participant's involvement results in unforeseen harmful experience for the participant. As far as possible steps must be taken to diminish this risk.
- The anonymity of the participant with reference to the information shared during interviews must be protected.
- The effective notification and communication with interviewee about the nature of the study. Adequate communication must take place and
- The reduction of risk associated with exploitation.

All ethical issues, aligned with those mentioned above, were considered during each empirical phase of this study, namely in the quantitative phase and the qualitative phase of both the pilot and the main study. In the quantitative component of the pilot and main study, an introduction with a description of the study was provided at the start of the questionnaire which includes a paragraph stating that participation in the survey was voluntary. (See Annexure 6A). Anonymity was maintained since no names were requested by the questionnaire.

In the qualitative phase, each of the five participants received a consent form (two in the pilot and three in the main study) (See Annexure 7A). The consent form described all the features of the study in terms of purpose, procedures and benefits, as well as the participants' rights to participate voluntarily and to withdraw at any time, or have their data withdrawn. Overall, the confidentiality and anonymity of participants, together with their informed consent to participate in this study, ensured that the study complied with ethical codes of practice.

5.8 Chapter summary

This chapter outlined the empirical plan that will be followed by this research study. The methodological approach was discussed before the comprehensive details of the embedded mixed method research design to meet the fourth and fifth research objectives of this study were presented. Validity, reliability and ethical considerations pertaining to the study were also discussed.

The next chapter presents the statistical analysis of data collected in the first empirical phase of this study. Robust analysis of quantitative data in the following chapter (as described in section 5.6.2 of this chapter) yields important findings from which a Model can be developed to meet the ultimate objective of this research, and thereby support and drive OpEx in the South African pharmaceutical industry.

CHAPTER SIX

QUANTITATIVE STUDY RESULTS AND DISCUSSION

'In God we trust, all others bring data.'

- Dr William Edward Deming

This chapter presents the results and discussion of the quantitative component of the main research study and thereby addresses the fourth research objective outlined in Chapter One, which is to conduct a focused study on Quality Management Practices, based on data collected from selected manufacturers of Category A medicines in the pharmaceutical industry in South Africa. Accordingly, the statistical analyses of the data collected from selected manufacturers of Category A medicines are discussed and presented in five content sections in this chapter, as illustrated by Figure 6.1.

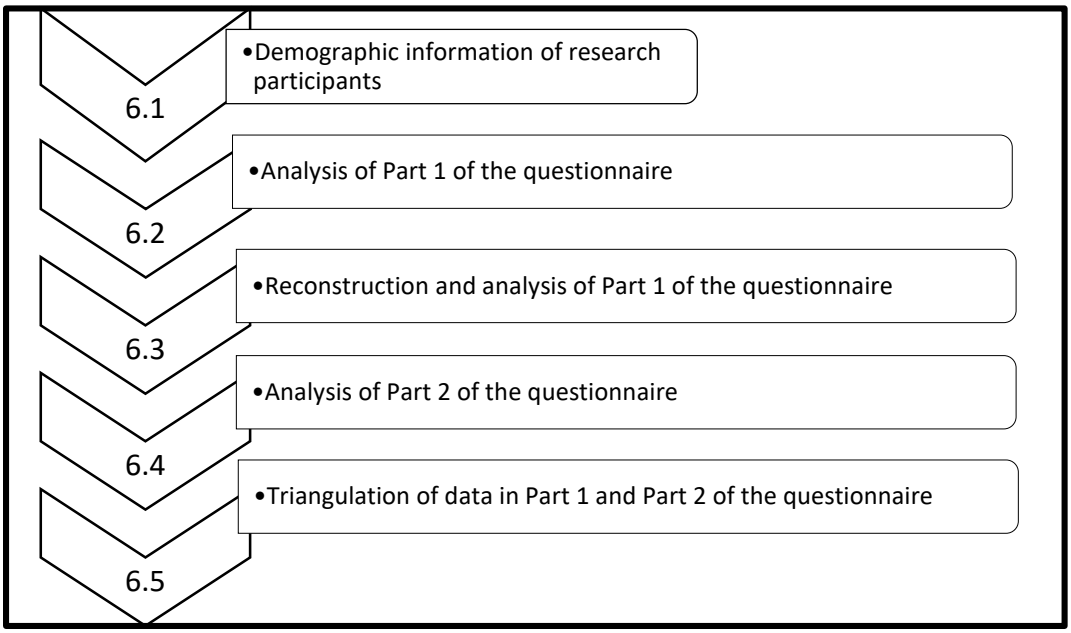


Figure 6.1: Overview of Chapter Six (Developed by the Researcher)

The first section of this chapter advances demographic information of the research participants. Section two of the chapter presents research findings obtained from the analysis of part one of this study's questionnaire with the intention of understanding the relationship between the specific variables: 'Quality Management Practices', 'Quality Culture' and 'Climate during quality management' in selected South African pharmaceutical organisations. Section three reconstructs the latent variables discussed in section two and tenders a framework for the model to be developed in Chapter Seven. Section four

presents the findings of the analysis of part two of this study's research questionnaire on the cultural traits of South African pharmaceutical organisations, and section five is a summary of the triangulation of data from section three and four.

The order in which the sections are presented follows the sequence of the four aims of the questionnaire as discussed in Chapter Five. Section two addresses the exploration of the relationship between Quality Management Practices and Quality Culture in the South African pharmaceutical industry. Section three measures the current OpEx level in the South African pharmaceutical industry across the dimension represented by reconstructed questionnaire. Section four establishes an OCAI culture types profile for the South African pharmaceutical industry and section five determines if there is a relationship between OCAI culture types and the dimensions of OpEx. This chapter concludes with a summary of findings.

6.1 Demographic information of research participants

The MCC provided the researcher with a list of names of all the GMP licenced pharmaceutical manufacturing organisations on record at the time that this study commenced. From April to May 2017, initial telephonic contact was made with the 30 organisations that were confirmed to have current GMP manufacturing licences. A follow-up email was sent to a contact person introducing this study. From June to September 2017 the research questionnaire was sent to all 30 organisations, requesting that four people in each organisation complete it. The research questionnaire consisted of two parts (part one evaluating QMS practices and part two evaluating organisational culture). Individuals in four specific roles in each pharmaceutical manufacturing organisation were requested to complete the questionnaire, in order for the researcher to profile the organisation as a whole. These were the Quality Manager (or management representative), the Production Manager (or management representative) and two people who work on the manufacturing line (operators). All research participants were informed that participation was entirely voluntary. The researcher offered to sign a non-disclosure agreement (NDA) if required. One organisation requested an NDA be

signed. The research questionnaire that was distributed to organisations is appended in Annexure 6A.

Eleven complete sets of responses consisting of four responses per organisation were returned. Two organisations provided the responses of only their Quality Manager and Production Manager (no operator data). A further four organisations returned only the response of their Quality Manager. Thus in total, 17 responses were obtained, which constituted a response rate of 57%. Nulty (2008) cites Babbie (1973) who asserts that 50% is regarded as an acceptable response rate for social research where questionnaires are not physically delivered to and collected from research participants. He mentions a study on 175 surveys in five top management journals which found that the overall average response rate was 55.6%.

It is noteworthy that six organisations responded by stating that they were not able to participate in the study (three via email; three telephonically). Three organisations who telephonically stated that they were not prepared to take part in the study were also not prepared to send a confirmation email that they declined the invitation to participate. Seven organisations did not respond to any requests for data.

6.2 Quantitative analysis: Questionnaire part one

The individual research variables (questions) that form part one of the questionnaire are shown in Table 6.1. This part of the questionnaire consisted of 33 individual research variables. All the variables are directly related to the management of quality in three areas, as highlighted in the literature presented in Chapter Two and Three. These areas are ‘Quality Management Practices’, ‘Quality Culture’ and ‘Organisational Climate during management of quality’. Part one of the questionnaire which was distributed can be referred to in Annexure 6A. Table 6.1 contains the unique variable names assigned to each question in part one of the research questionnaire.

Table 6.1 Question/Statement variable names

Question/Statement (Rated on a descriptive lickert scale from 1 to 7)	Variable
Section B: Quality Management Practices – Importance of Quality Management Practices	
The overall perception of quality management in our organisation.	QMP 1
The degree of importance attributed to always following prescribed Quality Management Practices in our organisation.	QMP 2
The degree of training on any basic quality tools (flow diagrams, check sheets, histograms, scatter diagrams, control charts, Pareto analysis and fishbone diagrams, 5s's) in our organisation.	QMP 3
The degree of shared responsibility in our organisation for the management of equipment. (Does each section/department only concern themselves with the proper functioning of their own equipment, or is there a sense of shared responsibility for the organisation's equipment?)	QMP 4
The extent to which risk management tools are an attribute of Quality Management Practices in our organisation.	QMP 5
The extent to which project management and planning tools are an attribute of Quality Management Practices in our organisation.	QMP 6
The extent to which a focus on waste reduction is a characteristic of the Quality Management Practices in our organisation.	QMP 7
The degree of importance attributed to incoming raw material inspection and validation.	QMP 8
The extent to which having a standardized system for supplier classification ensures uniform practices defining audit interval, scope, intensity and duration of supplier audits.	QMP 9
Section C: Quality Culture – Shared values that promote quality management	
In our organisation, we have a shared "mind-set", or shared "set of values" about processes, systems, infrastructure and our organisation in general.	QC 1
Customer satisfaction is a priority at every level in our organisation (i.e. major component of everyone's job description), and it is clearly manifested just by talking to them or watching them work.	QC 2
Leadership of our organisation provides venues, time and resources for cross-functional training, quality training and team activities.	QC 3
Every person in our organisation understands what "quality work" is, and executes it every time.	QC 4
Our organisation monitors activity in order to identify non-value added activities and finds ways to reduce it.	QC 5
Quality is a super-ordinate value in the departments within our organisation.	QC 6
We respect internal customers in our organisation.	QC 7

We use customer feedback to establish if we have satisfied external customers in our organisation.	QC 8
Every person knows his/her contribution in attaining goals of the organisation and is prepared to handle the implications of not meeting them.	QC 9
Our organisation has a collaborative approach with suppliers.	QC 10
Top management of our organisation is involved (anything more than just simple awareness that it is taking place) with internal audits in our organisation.	QC 11
Reduced cycle times is a focus area that is shared by all departments in our organisation.	QC 12
Reduction in rejections (e.g. OOS, OOT, non-conforming documents and others) is a focus area that is shared by all departments in our organisation.	QC 13
Delivery reliability is a focus area that is shared by all departments in our organisation	QC 14
Section D: Quality Climate – Conditions that promote values and support quality management	
The degree of alignment of our organisation's overall business strategy and the quality strategy of our organisation.	OC 1
The degree to which sales focus (based on KPIs) in my organisation overrides quality management in my organisation.	OC 2
Level of agility of my organisation's Quality Management Practices with regard to external factors (How responsive is the quality department to organisational needs, e.g. document requirements, when an external factor such as a competitor threat presents itself?)	OC 3
Level of agility of the entire organisation in response to a change in quality management requirements, e.g. regulatory requirement or continuous quality improvement initiative.	OC 4
Aside from the regulated requirement of change control management, when a change is required by my organisation (business or quality management change such as significant budgetary change or staff movement), is it standard practice to conduct a risk or impact assessment for every change before a decision is taken to change?	OC 5
The degree to which innovation in Quality Management Practices is encouraged in my organisation to promote continuous internal improvement.	OC 6
The degree to which innovation in Quality Management Practices is encouraged in my organisation to promote external (customer/ MCC/ stakeholder) satisfaction.	OC 7

The degree to which innovation is driven in my organisation by marketing requirements.	OC 8
The degree to which innovation is driven in my organisation by research and development (R&D) requirements.	OC 9
The degree to which innovation is driven in my organisation by Pharmaceutical Quality Management System (PQMS) requirements.	OC 10

When the individual variables of this research instrument were aggregated, they were transformed into compound latent variables which served as constructs to measure 'Quality Management Practices', 'Quality Culture' and 'Organisational Climate during quality management' respectively. The latent variables were created by calculating the sum of the responses that represented a particular construct as follows:

- **Quality Management Practices (QMP)** = QMP1 + QMP2 + QMP3 + QMP4 + QMP5 + QMP6 + QMP7 + QMP8 + QMP9
- **Quality Culture (QC)** = QC1 + QC2 + QC3 +QC4 + QC5 + QC6 + QC7 + QC8 + QC9 + QC10 + QC11 + QC12 + QC13 + QC14
- **Organisational Climate (pertaining to quality management) (OC)** = OC1 + OC2 + OC3 + OC4 + OC5 + OC6 + OC7 + OC8 +OC9 + OC10

6.2.1 Data reliability

Prior to the discussion on the findings of data analysis, it is important to verify the reliability of data. Reliability is measured using Cronbach's Alpha coefficient. Tavakol and Dennick (2011) consider a reliability coefficient of 0.70 or higher as acceptable. The results of the Cronbach Alpha coefficients for each of the individual research variables are presented in Annexure 6B. The reliability of each different section (latent variables) of part one of the questionnaire is displayed in Table 6.2.

Table 6.2 Reliability Analysis

Section	No of items	Cronbach's Alpha
Quality Management Practices	9 variables	0.908
Quality Culture	14 variables	0.954
Quality Climate	10 variables	0.895

Reliability analysis shows that each of the questionnaire sections has a value greater than 0.70 which indicates a high degree of acceptable and consistent scoring for the different sections of this part of the questionnaire.

6.2.2 Descriptive statistics

Descriptive statistical techniques are used to describe the basic features of the data in a study. They provide simple summaries about the sample and present data in a meaningful way such that patterns might emerge from the data (Field 2009). The proceeding section discusses the descriptive statistical analysis that was performed for this study.

6.2.2a Univariate analysis of Quality Management Practices (Section B)

Participants of this study reported that activities and the attitudes toward quality management activities in South African pharmaceutical manufacturing organisations are predominantly positive. Univariate graphs in Annexure 6C revealed the following about Quality Management Practices in these organisations:

- 84% of the participants reported that the overall perception of quality management in their organisation is positive.
- 91% of the participants stated that it is important in their organisations to always follow the prescribed Quality Management Practices.
- 67% of the participants reported that substantial training on quality tools took place in their organisations.
- 52% of the participants agreed that there is a degree of shared organisational responsibility towards the proper functioning of the organisation's equipment.
- 77% of the participants agreed that the use of risk management tools is an attribute of Quality Management Practices in their organisation.
- 75% of the participants stated that project management and planning tools are a component of Quality Management Practices in their organisation.
- 77% of the participants agreed that the reduction of waste is a focal point of their organisation's Quality Management Practices.
- 75% of the participants agreed that incoming raw material inspection and validation are important Quality Management Practices in their organisation.

- 94% of the participants felt that having a standardised system for supplier management ensures uniform Quality Management Practices.

Based on the foregoing statements this study deduces that a general trend in South African pharmaceutical organisations is that employees have a positive attitude towards quality management.

6.2.2b Univariate analysis of Quality Culture (Section C)

A univariate graph reflecting participants' perceptions on Quality Culture is also presented in Annexure 6C. From this graph, the following statements about Quality Culture, or 'shared values' in South African pharmaceutical manufacturing organisations can be made:

- 82% of the participants agreed that their organisation had a shared 'mind-set' or 'shared set of values' about processes, systems and infrastructure.
- 72% of the participants agreed that customer satisfaction is a priority at every level in their organisation, and is clearly manifested by just talking to them or watching them work.
- 71% of the participants reported their organisation's leadership provides venues, time and resources for cross-functional training, quality training and team activities.
- 73% of the participants agreed that every person employed by their organisation understands what 'quality work' is and executes it every time.
- 63% of the participants reported their organisation monitors activity in order to identify non-value added activities and finds ways to reduce it.
- 79% of the participants reported that quality is a superordinate value within their organisation.
- 78% of the participants indicated that internal customers are respected in their organisations.
- 79% of the participants indicated that customer feedback is used in their organisation to establish if external customers are satisfied.
- 73% of the participants reported that every person in their organisation knows what his/her contribution in attaining quality goals of the

organisation is, and is prepared to handle the implications of not meeting them.

- 77% of the participants felt that their organisation has a collaborative approach with suppliers.
- 60% of the participants indicated that top management in their organisations is involved with internal audits.
- 61% of the participants agreed that reduced cycle times are a focus area that is shared by all departments in their organisation.
- 84% of the participants agreed that reduction in rejections is a focus area shared by all departments in their organisation.
- 81% of the participants agreed that delivery reliability is a focus area that is shared by all departments in their organisation.

6.2.2c Univariate analysis of Quality Climate (Section D)

As reported in Chapter Three, Quality Climate and Quality Culture form a feedback loop. This section presents the findings on the overall environment, conflicts and leadership which are accepted as indicators of the Climate during quality management and are also a subset of Quality Culture. A univariate graph presenting this data is included in Annexure 6C and may be summarised as:

- 78% of participants believe that their organisation's overall Business Strategy and Quality Strategy are aligned.
- 70% of participants believe that their organisation is agile and responsive to external factors that pose a threat to quality management.
- 72% of participants believe that their organisation is agile and responsive to requirements that lead to continuous improvement of the Quality Management System.
- 63% of participants stated that risk management is a standard practice during decision making for business or quality management.
- 63% of the participants agreed that innovation in quality management is encouraged in their organisations to promote quality improvement.
- 68% of the participants agreed that innovation in quality management is encouraged to promote customer and stakeholder satisfaction.

- 71% of participants reported that innovation is driven by marketing requirements and 55% reported that innovation is driven by research and development (R&D)
- 70% of participants reported that innovation is driven by Quality Management System requirements.

The above statements reveal that the climate in South African pharmaceuticals is generally positive and supportive of quality management; however, 55% of participants believed that the sales focus of their organisation [based on personnel key performance areas (KPAs)] overrides quality management in the organisation.

6.2.3 Inferential statistics

Inferential statistical techniques are used to draw conclusions about a population based on a smaller sample taken from that population. Essentially inferential statistics are used to make judgments of the properties of a population, based on probability (Field 2009). The proceeding section discusses the inferential statistical analysis that was performed for this study.

6.2.3a Difference in proportions

To inferentially support the descriptive summations made from the evaluation of variables in the univariate analysis in section 6.2.2, a Chi squared test was conducted on each of the research variables to statistically determine if participants exhibited a strong preference towards a particular option (agree or disagree) in any of the variables. Certain options of the Lickert scale had less than five responses for selected variables thus the responses of the options 'agree to strongly agree' were aggregated into a single proportion representing 'agree'. Those responses of participants who selected 'disagree to strongly disagree' were aggregated into a single proportion representing 'disagree'. The third proportion was 'neutral'. For each variable the null hypothesis was set as **H_0: All proportions are equal**. Thus the alternate hypothesis is **H_1: All proportions are not equal.** The results of a Chi square analysis for all the research variables in each of the sections of the questionnaire namely Quality

Management Practices (QMP), Quality Culture (QC), and Climate during the management of quality (OC) can be seen in Annexure 6D.

The final results of a Chi test can be seen in Table 6.3. From this table, it can be concluded that a statistically significant difference exists between the proportion of participants who 'agreed' and the proportion of participants who 'disagreed' since the p-value for the Chi test on each variable was less than 0.05. Regarding each latent variable the following deductions can be made:

- Quality Management Practices: Most participants agree that the degree of importance placed on Quality Management Practices in South African pharmaceutical manufacturing organisations is high.
- Quality Culture: Most participants agree that the personnel in South African pharmaceutical manufacturing organisations share values that promote quality management.
- Climate during the management of quality: The climate in South African pharmaceutical manufacturing organisations promotes values that support quality management.

Table 6.3 Chi-square test for equal proportions

Variable label and theme	N	Std. Dev	Chi-Square	df	P-value
Section B: Quality Management Practices					
QMP1 Positive perception: Quality management	44	.509	51.318[a]	2	0.000
QMP2 Prescribed quality management	44	.582	29.455[b]	1	0.000
QMP3 Training quality tools	44	.821	24.591[a]	2	0.000
QMP4 Shared responsibility equipment	44	.750	8.773[a]	2	0.012
QMP5 Active risk management	44	.639	38.364[a]	2	0.000
QMP6 Active project management (planning)	44	.645	34.682[a]	2	0.000
QMP7 Active waste reduction	44	.639	38.364[a]	2	0.000
QMP8 Active incoming raw material inspections	44	.438	11.000[b]	1	0.001
QMP9 Uniformity promotes quality	44	.255	32.818[b]	1	0.000
Section C: Quality Culture					
QC1 Shared mind-set	44	.624	46.545[a]	2	0.000

QC2 Customer satisfaction priority	44	.689	30.864[a]	2	0.000
QC3 Leadership support	44	.761	27.318[a]	2	0.000
QC4 Quality understood	44	.561	32.909[a]	2	0.000
QC5 Eliminate non-value activities	44	.821	24.591[a]	2	0.000
QC6 Quality superordinate	44	.585	42.591[a]	2	0.000
QC7 Internal customer respected	44	.754	38.773[a]	2	0.000
QC8 Customer feedback used	44	.713	42.591[a]	2	0.000
QC9 Self-awareness re contribution	44	.689	30.864[a]	2	0.000
QC10 Collaborative suppliers	44	.639	38.364[a]	2	0.000
QC11 Leadership present	44	.813	13.136[a]	2	0.001
QC12 Reduced cycle times	44	.761	15.864[a]	2	0.000
QC13 Reduction of rejects	44	.660	51.318[a]	2	0.000
QC14 Delivery reliability	44	.668	46.682[a]	2	0.000
Section D: Quality Climate					
OC1 Strategy and quality aligned	44	.544	39.455[a]	2	0.000
OC2 Sales overrides quality	44	.829	8.909[a]	2	0.012
OC3 Agile quality management	44	.761	27.318[a]	2	0.000
OC4 Agile in response to external factors	44	.787	39.455[a]	2	0.000
OC5 Routine risk management	44	.791	18.182[a]	2	0.000
OC6 Innovative continual improvement	44	.818	18.318[a]	2	0.000
OC7 Innovation for customer satisfaction	44	.730	24.182[a]	2	0.000
OC8 Innovation due to market requirements	44	.761	27.318[a]	2	0.000
OC9 Innovation due to R&D	44	.930	12.318[a]	2	0.002
OC10 Innovation due to quality management	44	.849	28.955[a]	2	0.000

6.2.3b Relationship between Quality Management Practices, Quality Culture and Climate in the South African pharmaceutical industry

A correlation analysis was conducted to explore relationships between Quality Management Practices, Quality Culture and Climate in the South African pharmaceutical industry. When examining latent variables correlation coefficients add value since they indicate predictive relationships that can be exploited in practice. Field (2009), however, forewarns that considerable caution must be taken when interpreting correlation coefficients as the coefficient does not indicate the direction of causality. The coefficients say nothing about which variable causes the other to change, or if a third variable is responsible. The correlation coefficient is merely an indicator of the strength of association.

The Spearman rank correlation, also known as Spearman Rho, was used with non-parametric ordinal data. Spearman measures the degree to which, as one variable increases the other variable tends to increase or decrease. If the variables have a strong association, then the correlation coefficient will be close to +1 or -1 (with ±1 being a perfect positive or perfect negative correlation) and a weak association being close to 0 (with a value of 0 having no correlation). Spearman's correlation coefficient relates to linear relationships only. Table 6.4 shows the Spearman rank correlation coefficients for all three latent variables. The table demonstrates that these latent variables are all strongly correlated.

Table 6.4 Spearman Rho ranked correlations

Spearman's Rho Correlations				
		Section 1 QMP	Section 2 QC	Section 3 OC
Section B Quality Management Practices (QMP)	Correlation Coefficient	1.000	0.779**	0.750**
	Sig. (2-tailed)	.	0.000	0.000
	N	44	44	44
Section C Quality Culture (QC)	Correlation Coefficient	0.779**	1.000	0.767**
	Sig. (2-tailed)	0.000	.	0.000
	N	44	44	44
Section D Climate during quality management (OC)	Correlation Coefficient	0.750**	0.767**	1.000
	Sig. (2-tailed)	0.000	0.000	.
	N	44	44	44
**. Correlation is significant at the 0.01 level (2-tailed).				

The strength of association and linear dependency between the latent variables QMP and QC is +0.779. Consistent with literature (Evans and Lindsay 2017; Gambi, Jørgensen, Boer, Carpinetti and Gerolamo, 2013; Knapp, 2010; Jancikova and Brycha, 2009 and McNabb and Sepic, 2005) presented in Chapter Three, it can be inferred that the degree of importance attributed to Quality Management Practices in South African pharmaceutical organisations is strongly associated with the Quality Culture in these organisations. This study cannot assume the direction of this relationship. However, it supposes that the stronger the Quality Culture in an organisation, the higher the regard for Quality Management Practices that organisation. The supposition about this relationship

will be examined with multicollinearity and Regression analysis after Correlation analysis is discussed.

Spearman Rho tests also indicate significant statistical correlations between QC and OC and between OC and QMP. The correlation coefficients for these latent variables are 0.767 and 0.750 respectively. These results support the supposition that climate during quality management is associated with Quality Culture (Jacobs 2015; Weeks *et al.* 2004; McNabb and Sepic, 1995) since it is a subset of Quality Culture. Furthermore, Quality Management Practices are influenced by Quality Culture and the Climate during quality management.

The bivariate Spearman Rho analysis was then used to quantify the relationship between selected individual variables within the latent variables identified above. Each individual variable on Quality Management Practices was assessed against the individual variables measuring Quality Culture and Climate during quality management. All the results of this analysis were presented in Annexure 6E. However, the proceeding section discusses only the highest correlations above r = 0.60, at significance level of 0.01 in a two-tailed test. These significant findings support this study's inference that culture and climate have an impact on Quality Management Practices, and the following deductions are made:

The overall perception of Quality Management Practices in a South African pharmaceutical organisation is strongly associated with a shared set of values in an organisation (Annexure 6E Column 1; Row 1). When the culture of an organisation emphasises 'understanding what quality is', this promotes Quality Management Practices (Column 1; Row 4) in the organisation. A culture that values leadership that is present and supportive has a positive influence on Quality Management Practices in an organisation (Column 1: Row 11 and Row 3). Customer satisfaction and delivery reliability are also values (Column 1; Row 2 and Row 14) that promote Quality Management Practices. Climatic characteristics during the management of quality that promotes the importance of Quality Management Practices in an organisation are when the overall Business Strategy and Quality Strategy in an organisation are aligned (Column 1; Row 15), when innovative continual improvement takes place (Column 1: Row

20) and when innovation due to quality management requirements takes place (Column 1; Row 24).

Reducing the number of rejected products and delivery reliability (Column 2; Row 13 and 15) are cultural values strongly associated with always following the prescribed Quality Management Practices in an organisation. When the overall Business Strategy and Quality Management Strategy are aligned (Column 2; Row 1) following the prescribed Quality Management Practices becomes important in that organisation.

In an organisation where 'understanding quality' and having 'present' leadership is embedded as cultural values, 'training to manage quality' is promoted (Column 3; Row 4 and 11). Furthermore, it can be deduced that when quality management training is a featured element of organisational climate, the overall Business Strategy and the Quality Management Strategy are naturally aligned (Column 3; Row 1). During the management of quality such an organisation is agile in response to external factors (Column 3; Row 18) and innovative continual improvement (Column 3; Row 20) takes place.

Quality Management Practices that involve active risk management typify organisations where quality management is a subordinate value (Column 5; Row 6). Other values in these organisations include emphasis on 'reduced cycle times and reject products' (Column 5; Row 12 and 13) and 'delivery reliability' (Column 5; Row 14). Climatic characteristics include: Organisational strategy and Quality strategy are aligned (Column 5; Row 15), agility in response to external factors (Column 5; Row 18), innovative continual improvement (Column 5; Row 20) and where innovation is encouraged for customer satisfaction and quality management system requirements (Column 5; Row 21 and 24).

Quality Management Practices that involve active project management are evidence of a Quality Culture where leadership that is present and supportive is a shared value (Column 6; Row 11 and 3). Another common cultural value that promotes active project management is the importance placed on a common understanding of quality by all employees (Column 6; Row 4). Other values are

a focus on the reduction of reject products (Column 6; Row 13) and delivery reliability (Column 6; Row 14). Climatic attributes are: Organisational Strategy and Quality Strategy are aligned (Column 6; Row 15) and innovative continual improvement (Column 6; Row 20).

Quality Management Practices that focus on the elimination of waste stem from a culture where quality management is a subordinate value (Column 7; Row 6). The reduction in cycle times and product rejects (Column 7; Row 12 and 13) and delivery reliability (Column 7; Row 14) is valued. Climatic conditions that support the elimination of waste are agility in response to external factors (Column 7; Row 18), innovative continual improvement (Column 7; Row 20) and innovation for customer satisfaction and research and development requirements (Column 7; Row 21 and 23).

The above-mentioned deductions from statistical analysis yield a set of conclusions that assist this study with model development. These conclusions are presented in section 6.3 due to their closer relevance to the reconstructed research variables, and thus discussed in that section. Prompted by the significant number of results above 0.60 in the Correlation analysis, this study proceeds with a Regression analysis to develop a statistical prediction model in order to explain the relationship between the variables further. A normality test (see Annexure 6F) indicates the dependent QMP latent variable is normally distributed; therefore, linear Regression analysis is appropriate (Li, Wong, Lamoureux and Wong, 2012). Multicollinearity is, however, a concern when the two supposed independent variables are highly correlated to one another as is seen with QC and OC. Martz (2013) is of the view that multicollinearity reduces a statistical model's legitimacy and predictive power. Thus a variance inflation factor (VIF) test is performed to quantify the severity of multicollinearity in the data and thereby ensure that the outcome of the Regression analysis yields a reliable statistical model. The VIF of QC and OC is less than a value of 5 for both (Martz 2013); therefore, both QC and OC can be used as independent variables of QMP.

The result of the Regression analysis presented in Annexure 6F renders the statistical model for the relationship between QC, OC and QMP as proposed by

this study. This study concludes that the latent variables QC and OC are predictors of the dependent variable QMP. From this analysis, it can be deduced that the prediction model is statistically significant, based on a p-value of 0.00 in the ANOVA test at 95% confidence. In addition, r^2 is equal to 0.680, which is interpreted as 68% of any changes that take place in Quality Management Practices in pharmaceutical organisations in South Africa are due to a change that took place in Quality Culture and the Climate during the management of quality. The standardised beta coefficients of the model are 0.454 for QC and 0.419 for OC. Thus the impact of Quality Culture and Climate on Quality Management Practices during quality management are statistically close to each other.

6.3 Reconstructed latent variables: Indicators of culture

The latent variables in part one of the questionnaire are now reconstructed as this study progresses towards meeting the fifth objective, which is to develop a Model of Quality Management Practices that is supported by Quality Culture. Quality criteria such as those seen in international quality awards are capable of serving as dimensions of a Quality Model (Ladzani, 2016; Business Excellence Tools, 2016; Smit et al. 2011; Williams, 2008; Stading and Vokurka, 2003 and Adebanjo, 2001). For this purpose, the latent variables QMP, QC and OC are reconstructed to yield such dimensions which are intended to indicate the areas where organisations must evaluate their current levels of performance, identify and prioritise areas for improvement, integrate improvement actions into business plans and identify best practice. The Model should possess criteria that serve the same function as international quality award criteria, with the distinction that it is a Model specifically tailored to the needs of South African pharmaceutical organisations.

In Chapter Two of this study, Leadership, Strategy, Systems Approach, Customer Focus, Continual Improvement, Employee Empowerment, Fact-based Management, Supplier partnership, Training and Agility were identified as criteria that are both 'important areas in quality management' and 'indicators of Quality Culture'. This study now sets out to evaluate their suitability as dimensions of a Quality Model for the South African pharmaceutical industry.

Table 6.5 illustrates how the previous latent variables (QMP, QC and OC) have been reconstructed to form nine new variables. Prior to evaluating the aptness of the individual research variables to measure a particular dimension, Cronbach's Alpha coefficient was used to measure the internal reliability of each reconstructed latent variable to decide if it was internally reliable to be used. The Cronbach's Alpha coefficient for each new latent variable was above 0.70.

Table 6.5 Reconstructed latent variables: Indicators of Quality Culture

Indicator of culture	**Research variables (name indicates previous latent variable on quality management) and theme**	**Cronbach Alpha**
Leadership	QC11 – Top management are involved QMP1 – Organisational importance on following quality prescriptions QMP6 – Planning and project management part of quality	0.728
Strategy	QC6 – Quality is superordinate value in organisation QMP1 – Overall perception of quality in organisation OC4 – Aligned quality and business strategy	0.715
Systems Approach	QC1 – Shared mindset QC8 – Feedback loop to improve system QC14 – All departments prioritise delivery reliability OC3 – Organisation-wide responsiveness to quality	0.796
Customer Focus	QC2 – Customer satisfaction is priority QC7 – Internal customer respected OC7 – External customer/stakeholder satisfaction important	0.823
Continual Improvement	QC12 – Reduced cycle times QC13 – Reduction in rejections QMP7– Waste reduction characterises organisation OC4 – Innovation promotes continuous improvement	0.853

Employee Empowerment	QC4 – All employees understand what 'quality work' is QC9 – Each person knows what their contribution is and fulfils it and will handle implications QMP4 – Employees share responsibility of equipment to ensure good quality	0.791
Fact-Based Management	QC5 – Organisational activities monitored to manage quality QMP5 – Risk management is an attribute OC5 – Risk management in decision making	0.812
Supplier Partnership	QC10 – Supplier collaboration QMP8 – Value of incoming inspection QMP9 – Standardised supplier management	0.772
Training and Agility	QC3 – Quality and cross-functional training in organisation QMP3 – Training on basic quality tools OC 3 – Organisational agility: External factors OC 4 – Organisational agility: Quality requirements	0.808

It can be deduced that the composition of the reconstructed variables is internally reliable. Further evidence to support the aptness of the composition of the reconstructed latent variables are the conclusions of the bivariate Spearman Correlation analysis, as discussed in section 6.2. These conclusions identify the specific organisational values (culture) that directly support quality management. Essentially, these values are evidence of the presence of both Quality Management Practices and Quality Culture; thus it can be assumed that these are suitable for use as dimensions of the conceptual Model. The conclusions drawn from section 6.2 are:

- Present leadership is an attribute that constitutes a value which supports quality management in an organisation.
- Organisation emphasis on 'understanding what quality is' is an attribute which constitutes an organisation value where training in quality management is regarded as important. This is a value that supports Quality Management Practices
- Employee empowerment is an attribute that constitutes a value which supports quality management in an organisation.

- Importance placed on customer satisfaction is an organisational value that supports Quality Management Practices.
- Importance placed on delivery reliability is an attribute that constitutes an organisational value. During quality management a systems approach allows an organisation to uphold that value.
- Focus on waste reduction and reduced rejects are also organisational attributes that constitute values. These values lead to continual improvement in the organisation.
- Risk management is embedded in good quality management, and it is a feature of organisations where management based on facts is valued.
- The shared values of an organisation related to their Quality Management Practices constitutes that organisation's Quality Culture, and this supports effective quality management.
- When Business Strategy and Quality Strategy are aligned, it fosters a climate conducive to quality management.

Therefore, based on the conclusions in the foregoing section, this study finds that the reconstructed latent variables are suitable for comparative analysis with part two of the research questionnaire, which measures OCAI cultural traits. The comparative analysis will be discussed in section 6.5 following the analysis of OCAI traits in South African organisations. The reconstructed latent variables are now also regarded as suitable to be used as dimensions of the conceptual Model of Quality Management Practices being developed by this study.

6.4 Quantitative analysis: Questionnaire part two

Part two of the research questionnaire (also presented in Annexure 6A), explores the general culture landscape of pharmaceutical manufacturing organisations in South Africa on the basis of Cameron and Quinn (1999) competing values of culture. Table 6.6 displays the six multidimensional research variables in the questionnaire, each of which comprises four weighted dimensions. The dimensions measure the prevalence of a particular culture trait in an organisation. The traits are clan (family type trait), adhocracy (risk-taker type trait), market (competitive type trait) and hierarchy (rigid and structured type trait). Research

participants allocated a weight to each dimension. The total weight of each variable is computed by adding the four weighted dimensions, which add up to a total of 100.

Table 6.6 OCAI question/Statement variable names

Question/Statement	Variable
Variable 1: Dominant Characteristic	
The organisation is a very personal place. It is like an extended family. People seem to share a lot of themselves.	DC_C
The organisation is a dynamic and entrepreneurial place. People are willing to stick their necks out and take risks.	DC_A
The organisation is very results oriented. A major concern is with getting the job done. People are very competitive and achievement oriented.	DC_M
The organisation is a very controlled and structured place. Formal procedures generally govern what people do.	DC_H
Variable 2: Organisational Leadership	
The leadership in the organisation is generally considered to exemplify mentoring, facilitating, or nurturing.	OL_C
The leadership in the organisation is generally considered to exemplify entrepreneurship, innovation, or risk taking.	OL_A
The leadership in the organisation is generally considered to exemplify a no-nonsense, aggressive, results-oriented focus.	OL_M
The leadership in the organisation is generally considered to exemplify coordinating, organizing, or smooth - running efficiency.	OL_H
Variable 3. Management of Employees	
The management style in the organisation is characterized by teamwork, consensus, and participation.	ME_C
The management style in the organisation is characterized by individual risk taking, innovation, freedom, and uniqueness.	ME_A
The management style in the organisation is characterized by hard-driving competitiveness, high demands, and achievement.	ME_M
The management style in the organisation is characterized by security of employment, conformity, predictability, and stability in relationships.	ME_H
Variable 4. Organisation Glue	
The glue that holds the organisation together is loyalty and mutual trust. Commitment to this organisation runs high.	OG_C
The glue that holds the organisation together is commitment to innovation and development. There is an emphasis on being on the cutting edge.	OG_A

The glue that holds the organisation together is the emphasis on achievement and goal accomplishment.	OG_M
The glue that holds the organisation together is formal rules and policies. Maintaining a smoothly running organisation is important.	OG_H
Variable 5. Strategic Emphases	
The organisation emphasises human development. High trust, openness, and participation persist.	SE_C
The organisation emphasises acquiring new resources and creating new challenges. Trying new things and prospecting for opportunities are valued.	SE_A
The organisation emphasises competitive actions and achievement. Hitting stretch targets and winning in the marketplace are dominant.	SE_M
The organisation emphasises permanence and stability. Efficiency, control, and smooth operations are important.	SE_H
Variable 6. Criteria for Success	
The organisation defines success on the basis of the development of human resources, teamwork, employee commitment, and concern for people.	CS_C
The organisation defines success on the basis of having unique or the newest products. It is a product leader and innovator.	CS_A
The organisation defines success on the basis of winning in the marketplace and outpacing the competition. Competitive market leadership is key.	CS_M
The organisation defines success on the basis of efficiency. Dependable delivery, smooth scheduling, and low - cost production are critical.	CS_H

An overview of the prevailing cultural traits in South African pharmaceutical manufacturing organisations is displayed in Table 6.7 and also graphically depicted in Figure 6.2. Figure 6.2 also presents a comparison of the overall perception (reported as a percentage) to the perceptions obtained from the quality managers and the production managers in pharmaceutical manufacturing organisations in South Africa. Graphic depictions of anonymised results obtained from all the individual organisations that took part in this study are presented in Annexure 6G.

Table 6.7 Overall OCAI results: Cultural traits (in percentage)

Culture Types	All Organisations	QA Managers	Prod Managers
Clan	27	22	27
Adhocracy	15	12	14
Market	25	27	23
Hierarchy	33	39	37

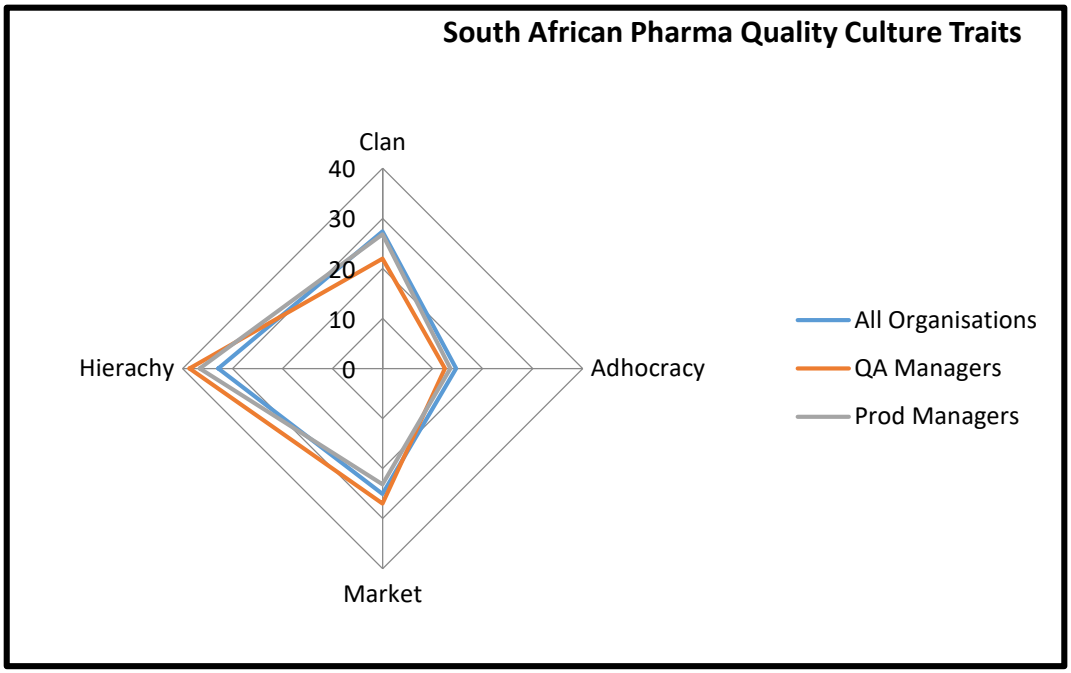


Figure 6.2: Overall OCAI results: SA Pharma

This study sets out to statistically determine if any culture trait was perceived to be more dominant than others. Thus, One-Factor ANOVA at 95% confidence was used (n=44). A null hypothesis was set as **H_0: The strength of the four different cultural traits in pharmaceutical manufacturing organisations in South Africa is equal to each other**. Thus the alternate hypothesis was **H_1: The strength of the four different cultural traits in pharmaceutical manufacturing organisations in South Africa is not all equal to each other.** The null hypothesis was rejected, and therefore, a Tukey Kramer pairwise comparison was done to determine if any pairwise differences between individual cultural trait groups exist. The results of this analysis are appended as Annexure 6H and summary of the pairwise comparisons are presented in Table 6.8 which follows.

Table 6.8: Tukey Kramer pairwise comparisons for overall Quality Culture traits

Overall Quality Culture	**Clan**	**Adhocracy**	**Market**	**Hierarchy**
Clan		Significant difference	No significant difference	No significant difference
Adhocracy	Significant difference		Significant difference	Significant difference
Market	No significant difference	Significant difference		Significant difference
Hierarchy	No significant difference	Significant difference	Significant difference	

Table 6.8 shows that, in terms of the overall Quality Culture of the South African pharmaceutical industry, there is no significant difference in the proportion of hierarchical culture and clan culture. There is, however, a significant difference in the proportion of hierarchical culture compared to adhocracy and market culture. There is no significant difference between the proportion of clan culture when compared to market culture. However, there is a significant difference between the proportion of clan culture when compared to the proportion of adhocracy culture. The proportion of adhocracy culture in South African pharmaceutical organisations is significantly smaller than any other culture type. Thus, Tukey Kramer confirms that the most dominant culture type is the hierarchical culture and the most inferior culture type is the adhocracy culture.

This study, therefore, deduces that the most prevalent culture trait representing the overall Quality Culture of the manufacturing organisations in South Africa is the hierarchical culture, measuring 33%. This finding is consistent with the highly structured and regulatory nature (Friedli *et al.* 2013) of the pharmaceutical industry. Jancikova and Brycha (2009) suggest that the significant attributes of the hierarchical culture are order, rules and regulations, uniformity and efficiency. It can be deduced that hierarchical cultural traits are vital as a dominant characteristic in the manufacturing organisation in the pharmaceutical industry as this facilitates compliance with GMP.

The clan type cultural trait and market-driven cultural trait are almost equally positioned as the second most prominent cultural trait representing the overall Quality Culture of the manufacturing organisations in the pharmaceutical industry in South Africa, measuring 25% and 27% respectively. Finally, data indicates that the adhocracy culture traits constitute merely 15% of the overall Quality Culture of manufacturing organisations in the pharmaceutical industry.

Consequently, this study concludes that mentorship and competitiveness are equally important to South African pharmaceutical manufacturing organisations. These traits are secondary to hierarchical traits but are also required to sustain compliance with GMP, which is consistent with the finding of Chapter Four of this study which found that a blend of cultural traits is required for success. At present, the pharmaceutical industry does not value adhocracy culture traits as much as the former three culture trait types. This study presumes that risk-taking cultural traits are in conflict with and contrast to hierarchical culture traits, which this study has proven to be the most valued in the South African pharmaceutical industry. It is worth noting, however, that on the basis of the findings of Chapter Four, it is believed that a certain degree of adhocracy is required during quality management for both continual improvement and risk management.

In addition to the overall Quality Culture profile discussed above, Annexure 6H also presents the ANOVA and pairwise comparisons of each of the six individual multidimensional variables measured by the OCAI, namely Dominant Characteristic, Organisational Leadership, Management of Employees, Organisational Glue, Strategic Emphasis and Criteria for Success. As with the overall Quality Culture traits, Annexure 6H shows that statistically unequal proportions of culture traits were found to be present in each of the multidimensional variables. The analysis presented below is done by examining the descriptive statistics (spider charts) and the results of inferential statistics (ANOVA and Tukey Kramer).

In terms of Dominant Characteristics, the proportion of clan culture (21%) is statistically significantly different to the proportion of hierarchical culture (42%). It is, however, not statistically significantly different to proportions of market-driven

(22%) or the adhocracy culture (14%). The proportion of adhocracy culture is only statistically significantly different to the hierarchy culture proportion. The proportion of market-driven culture is also only statistically significantly different to the hierarchical. Thus the proportion of hierarchical culture is statistically significantly different to all other culture types, and thereby this study confirms that hierarchical culture traits are the most dominant culture traits in South African pharmaceutical organisations.

In terms of Organisational Leadership, the proportion of adhocracy culture (13%) is statistically significantly different to the proportions of all other culture types. The proportion of adhocracy culture is statistically significantly different to the proportions of all other culture types. The proportion of market-driven culture is statistically significantly different to adhocracy but not clan culture or hierarchical culture. The Tukey Kramer test found that the proportions of hierarchical culture (31%), clan culture (29%) and market-driven culture (27%) are not statistically significantly different to each other. From this statistical analysis, this study assumes that employees believe that a blend of clan culture traits, hierarchical culture traits and market-driven culture traits are present in the leadership of pharmaceutical organisations. This study deduces that adhocracy culture traits in the leaders of South African pharmaceutical organisations are the least valued cultural traits to support quality management.

In terms of the Management of Employees, the proportion of clan culture (36%) is the largest and is statistically significantly different to the proportions of hierarchy culture (23%) and adhocracy culture (14%). However, it is not statistically significantly different to that of market-driven culture (27%); thus this study presumes that clan and market-driven culture traits are the two most prominent traits featured during the management of employees in South African pharmaceutical organisations. The proportion of adhocracy culture is statistically significantly smaller to the proportions of all other culture trait types, and this study deduces that the adhocracy culture is the least valued cultural trait during the management of employees. From this statistical analysis, it can be surmised that employees in South African pharmaceutical organisations believe that clan culture traits are valued during employee management. Similarly sized

proportions of hierarchical culture traits and market-driven culture traits are present in South African pharmaceutical organisations. However; this study concludes that these are overshadowed by clan culture traits.

In terms of Organisational Glue, the proportion of hierarchical culture (38%) is significantly statistically larger than all other culture types, and this study, therefore, deduces that the hierarchical culture traits are the most valued to promote cohesion in pharmaceutical organisations in South Africa. The proportions of clan culture (25%), market-driven culture (21%) and adhocracy culture (16%) are not statistically significantly different to each other, although adhocracy is the smallest and regarded by this study to be the least valued to promote cohesion. This study, therefore, presumes that hierarchical culture traits are the primary bonding agents in South African pharmaceutical organisations. However, to a lesser degree, a variety of clan, market-driven and adhocracy culture traits are also capable of facilitating cohesion.

In terms of the Strategic Emphasis, the proportions of hierarchical culture (29%), clan culture (28%) and market-driven culture (28%) are not statistically significantly different to each other. The proportion of adhocracy culture (16%) is statistically significantly different to all other culture types. The Tukey Kramer test thereby confirms that adhocracy culture traits are the least valued in pharmaceutical organisations to deploy strategies. Employees in South African pharmaceutical manufacturing organisations believe that a blend of the remaining three culture types, namely clan, market-driven and hierarchical culture traits are valued to emphasise and deploy the Quality Management Strategy in organisations in South Africa.

Finally, in terms of the Criteria for Success, identical to Strategic Emphasis above, the proportions of hierarchical culture (33%), clan culture (26%) and market-driven culture (26%) are not statistically significantly different to each other. The proportion of adhocracy culture (15%) is statistically significantly different to all other culture types. From this, this study concludes that the adhocracy culture traits are the least valued traits in pharmaceutical organisations as Criteria for Success. Employees believe that a blend of the

remaining three culture types, namely clan, market-driven and hierarchical culture is valued as criteria for success in pharmaceutical manufacturing organisations in South Africa.

A summary of the analysis of this section of Chapter Six, with supporting extracts taken from the review of the literature, is presented in Table 6.9 which follows:

Table 6.9 Descriptive summary of findings with associated literature that supports the findings from the analysis of research variables

Research variable	Allocation of cultural traits in organisations	Related extracts taken from the sources of literature reviewed in Chapters Two, Three and Four	Conclusion
Dominant Characteristic	Hierarchy 42% Clan 21% Market 22% Adhocracy 14%	The hierarchical nature of the global pharmaceutical industry is necessary to safe-guard the consumers of pharmaceutical products from harm (Jacobs and Signore, 2016; Haleem *et al*. 2014; Jacob, 2013; Woodcock, 2012). Empirically, this study confirms that hierarchy is the most dominant culture in the South African pharmaceutical industry. Second to hierarchy, clan and market-driven culture traits are equally dominant. The adhocracy culture is the least dominant culture in the South African pharmaceutical industry.	The hierarchy culture type is the most prevalent culture type in the South African pharmaceutical industry according to each research variable that was analysed in this part of the study, except for the variable Management of Employees. This reiterates the general structured nature of pharmaceutical organisations due to regulation. Statistically similar proportions of the clan and market-driven culture are present in South African pharmaceutical organisations, except during the Management of Employees. Research variables that explored Dominant Characteristics, Organisational Leadership, Strategic Emphasis and Criteria for Success highlights that the difference in the proportion of clan culture and market-driven culture is never more than 2%. The proportion of adhocracy culture is consistently the lowest in all research variables (never more than 16%). Continued on next page…/…
Organisational Leadership	Hierarchy 31% Clan 29% Market 27% Adhocracy 13%	Leadership is based on a combination of subjective factors (personality traits) and objective factors (managerial ability). Jabnoun and Sedrani (2005) argue that a clear, assertive vision underpinned by suitable culture traits is a characteristic of good leadership during effective quality management. A deduction made from the empirical results is that almost equal prominence of hierarchical culture, clan culture and market culture traits are valued as good leadership characteristics.	
Management of Employees	Hierarchy 23% Clan 36% Market 27% Adhocracy 14%	The empirical result of the analysis of this variable suggests that, during the management of employees, a significantly higher proportion of clan culture is required. This aligns with the view of Tsai (2011) who holds that culture influences leadership behaviour, which in turn is associated with employee job satisfaction and employee morale, therefore, guidance and mentorship is important. This will also have an impact on an organisation's strategy.	

Organisational Glue	Hierarchy 38% Clan 25% Market 21% Adhocracy 16%	This empirical finding is that the hierarchy serves as organisational glue. Hierarchical standardisation of procedures leads to everyone in the organisation knowing what to do. Hildebrant *et al.* (1991) reported that communication and a common understanding are essential to keep the organisation together; thus this study also deduces that Organisational Culture is the foundation of Quality Culture and that Quality Culture, in turn, is a primary driver of internal organisational collaboration.	In summation, a similar profile (proportions of culture) was noted in all the research except the Management of Employees. This study presumes that hierarchy is vitally important in the pharmaceutical industry; however, the requirements to sustain a quality management system or a quality strategy are not the same as the requirement to develop them. People are an important factor in the sustainability of a quality management system or a quality strategy (Malhi 2013; Friedli, Basu, Gronauer and Werani, 2010 and Coffey, 2008), and therefore, this research study deduces that sustainability is dependent on the quality values of the people (employees) in an organisation.
Strategic Emphasis	Hierarchy 29% Clan 28% Market 28% Adhocracy 16%	Empirically this demonstrates that a variety of culture types sets the foundation for Quality Management Strategy. Furthermore, according to Evans and Lindsay (2017) and Evans (2017), a good strategy is an organisation's competitive advantage. Strategy identifies the critical success factors of an organisation. In terms of strategy in pharmaceutical organisations, a blend of hierarchy, clan and market-driven culture traits are required	
Criteria for Success	Hierarchy 33% Clan 26% Market 26% Adhocracy 15%	Similar to the empirical finding of the Strategic Emphasis variable, a variety of cultural traits are presumed to be valued as Criteria for Success in South African pharmaceutical organisations. Jabnoun and Sedrani (2005) argue that quality management requires both control and exploration to achieve desired performance, as well as standardisation and decentralisation	

This data analysis summary in Table 6.9 confirms that a variety of cultural traits which constitute the Quality Culture are required to successfully manage quality in pharmaceutical organisations, which is consistent with the findings of Chapter Four of this study. Furthermore, the cultural traits are not equally weighted. Thus, this study deduces that certain cultural traits are capable of supporting certain Quality Management Practices better than others.

6.5 Triangulation of Part One and Part Two Quantitative Data

This section examines the association between the dimensions for the conceptual Model that are proposed in section 6.3, and general prevailing cultural traits in South African pharmaceutical organisations, as discussed in section 6.4. The triangulation of the data in Correlation analysis allows this study to determine if a particular culture trait is more significant than others for a particular dimension of the Model. The p-values of Spearman correlations are used to determine which of the four cultural traits has the most significant association with the dimensions in the framework for the conceptual Model.

The results of this analysis are displayed in Table 6.10. The table displays the correlation coefficient and the p-value and will guide the design of the conceptual Model in Chapter Seven.

Table 6.10 Correlations between OpEx Dimensions and OCAI culture types

Correlations					
		Clan	Adhocracy	Market	Hierarchy
Strategy	Correlation Coefficient	0.423	0.384	-0.347	-0.423
	Sig. (2-tailed)	0.004	0.010	0.021	0.004
Leadership	Correlation Coefficient	0.515	0.408	-0.384	-0.468
	Sig. (2-tailed)	0.000	0.006	0.010	0.001
Employee Empowerment	Correlation Coefficient	0.510	0.354	-0.529	-0.395
	Sig. (2-tailed)	0.000	0.018	0.000	0.008
Customer Focus	Correlation Coefficient	0.442	0.415	-0.486	-0.357
	Sig. (2-tailed)	0.003	0.005	0.001	0.017
Continual Improvement	Correlation Coefficient	0.490	0.422	-0.433	-0.436
	Sig. (2-tailed)	0.001	0.004	0.003	0.003
Supplier	Correlation Coefficient	0.262	0.476	-0.224	-0.448
	Sig. (2-tailed)	0.086	0.001	0.143	0.002
Training and Agility	Correlation Coefficient	0.504	0.411	-0.421	-0.499
	Sig. (2-tailed)	0.000	0.006	0.004	0.001
Fact based Management	Correlation Coefficient	0.420	0.488	-0.433	-0.397
	Sig. (2-tailed)	0.005	0.001	0.003	0.008
Systems Approach	Correlation Coefficient	0.454	0.562	-0.494	-0.499
	Sig. (2-tailed)	0.002	0.000	0.001	0.001

Fenton and Neil (2013) point out that formally established statistical confidence in a relationship (between research variables) is not determined merely by the correlation coefficient, but also by the number of pairs in the data. Thus, if there are very few pairs then the coefficient needs to be very close to 1 or –1 for it to be deemed 'statistically significant', however, if there are many pairs - as in the case of the data set in this study - then a coefficient closer to 0 can still be considered 'highly significant'. Therefore, to statistically determine if a correlation is significant in this empirical analysis, the p-value approach may be used.

At 95% confidence (n=44) a null hypothesis was set for each reconstructed latent variables as **H_0: The reconstructed latent variable is unrelated to a cultural trait in pharmaceutical manufacturing organisations in South Africa**. Thus the alternate hypothesis was **H_1: The reconstructed latent variable is related to a cultural trait in pharmaceutical manufacturing organisations in South Africa**. The cultural trait that yields the lowest p-value for a particular dimension is regarded as the most significant to that dimension. From this analysis the following deductions are made:

- The clan culture and hierarchical culture has the most significant influence on the strategy dimension. Statistically, it is regarded to have the most explanatory power over strategy, when compared to adhocracy culture and market culture.
- The clan culture has the most significant influence on the leadership dimension. Statistically, it is regarded to have the most explanatory power over leadership, when compared to the hierarchical, adhocracy culture and market culture.
- The clan culture and market culture has the most significant influence on the employee empowerment dimension. Statistically, it is regarded to have the most explanatory power over employee empowerment, when compared to the hierarchical culture and adhocracy culture.
- The market culture has the most significant influence on the customer focus dimension. Statistically, it is regarded to have the most explanatory power over customer focus, when compared to clan culture, adhocracy culture and hierarchical culture.

- The clan culture has the most significant influence on the continual improvement dimension. Statistically, it is regarded to have the most explanatory power over continual improvement, when compared to adhocracy culture, market culture and hierarchical culture.
- The adhocracy culture has the most significant influence on the supplier management dimension. Statistically, it is regarded to have the most explanatory power over supplier management, when compared to clan culture, market culture and hierarchical culture.
- The hierarchical culture has the most significant influence on the training and agility dimension. Statistically, it is regarded to have the most explanatory power over training and agility, when compared to clan culture, adhocracy culture and market culture.
- The adhocracy culture has the most significant influence on fact-based management dimension. Statistically, it is regarded to have the most explanatory power over fact-based management, when compared to clan culture, market culture and hierarchical culture.
- The adhocracy culture has the most significant influence on the systems approach dimension. Statistically, it is regarded to have the most explanatory power over systems approach, when compared to clan culture, market culture and hierarchical culture.

These deductions may be summarised as the clan culture has the most explanatory power over Strategy, Leadership, Employee Empowerment and Continual Improvement; the adhocracy (risk taker) culture has the most explanatory power over Supplier Partnership, Fact-Based Management and Systems Approach; the Market culture has the most explanatory power over Employee Empowerment, and Customer Focus and the Hierarchical culture has the most explanatory power over Strategy and Training and Agility.

6.6 Chapter summary

This chapter has achieved the aims of quantitative research that were stated in Chapter Five. Based on the statistical analysis presented in this chapter, four substantive findings emerged. First, research gathered that Quality Culture and the climate are independent variables of Quality Management Practices. A statistically significant model was developed from data which indicated that 68% of any change in Quality Culture in an organisation would result in a change in Quality Management Practices.

Second, on the foundation that shared values about quality constitutes Quality Culture, this study deduced that the dimensions of a Model of Quality Management Practices should be Strategy, Leadership, Systems Approach, Employee Empowerment, Training and Agility, Continual Improvement, Customer Focus, Management based on Facts. Bivariate analysis indicated that these dimension gauge Quality Management Practices but are simultaneously indicators of culture.

The third substantive finding of this chapter is the illustration of the current landscape of the South African pharmaceutical industry provided, in terms of the proportion of particular culture traits that support Quality Management Practices in manufacturing organisations. The hierarchical culture is the most dominant culture trait in pharmaceutical manufacturing organisation due to GMP. The second and third most dominant culture traits are clan culture and market culture respectively. This study found that there is no significant difference in the proportions of these two cultural traits. The least dominant culture trait in pharmaceutical organisations in South Africa is the adhocracy culture trait.

The fourth and most important finding of this chapter is the identification of significant relationships between the dimensions of quality management (also referred to as indicators of Quality Culture in Chapter Three) and the culture traits. The clan culture is the most important for Strategy, Leadership, Employee Empowerment and Continual Improvement. The adhocracy culture is the most important for Supplier Management, Fact-Based Management and Systems

Approach. The market culture is the most important for Employee Empowerment and Customer Focus. The hierarchical culture is the most important for Strategy and Training and Agility. These findings serve as a foundation for model development in the next chapter. These dimensions of quality are the building blocks of the Model being developed. This study will set out to qualitatively understand how and why culture supports Quality Management Practices within these dimensions in South African pharmaceutical organisations.

Hereby this chapter has also met the fourth objective of this research study. This focused deductive quantitative study research demonstrates that the indicators of Quality Culture can be practically measured. It is postulated that it is viable to include the nine indicators of Quality Culture as concepts to provide a framework for a Model of Quality Management Practices. The design of this Model will be discussed in the next chapter.

CHAPTER SEVEN
MODEL DEVELOPMENT

'It is not enough to do your best; you must know what to do, and then do your best.'

- Dr William Edward Deming

This chapter fulfils the final research objective through the construction of a conceptual Model of Quality Management Practices. Rooted in the theory presented in Chapters Two, Three and Four, and in the findings of quantitative data analysis presented in Chapter Six, this chapter proposes a proposed Model. Thereafter the chapter initiates the second empirical phase of this research design, namely the qualitative component of this research. Qualitative data collection and analysis yields the final research data needed for the development of the conceptual OpEx Model for South African pharmaceutical organisations, ensuring that the Model is ready to use. It also illuminates the key reasons (related to Quality Culture) why the Model adds value to the South African pharmaceutical industry.

This chapter comprises of three main sections. The first section integrates literature and the findings of the quantitative data presented in the preceding chapters, to develop a proposed Model. The second section of this chapter analyses qualitative data to explore the validity of the concepts included in the proposed Model, thereby uncovering the reasons why Quality Culture influences quality management. The third section optimises the Model on the basis of the findings of section two. The chapter concludes with an acknowledgement of the limitations of the conceptual Model and a chapter summary.

7.1 Development of the proposed Operational Excellence Model

Model development in this study commences with a discussion on the requirements of a Model. Thereafter, a reflection on the 'study thus far' enables a proposed conceptual OpEx model to be developed in the subsequent section of this chapter.

7.1.1 General requirements pertaining to Frameworks, Models and Theories in literature

Nilsen (2015) provides this study with guidance in developing a Model, by outlining the overarching aims of Frameworks, Models and Theories for practical use in industry. Models are intended to describe or guide the process of translating research into practice. Models help users to understand the factors that influence implementation outcomes and thereby users can evaluate the success of implementation.

Frameworks, on the other hand, only provide an overview depicting the structure of variables that are important to a phenomenon. Frameworks communicate the relations assumed to account for a phenomenon, but do not describe the variable in detail. Therefore, this research sets out to develop a Model, rather than a Framework since a Model provides greater detail about the variables that are important to a phenomenon. According to Nilsen (2015), Cooper and Schindler (2014) and Shafique and Mahmood (2010). Models do not explain in as much detail how or why specific variables lead to certain events as literature or theory does. This means that Models are a deliberate simplification of the theory on a specific phenomenon.

Essentially, Models do not have to be a completely accurate representation of reality, in order to add value. Shafique and Mahmood (2010) state that, by simply illustrating a system with its components and the relationships between components and subcomponents, a model provides users with assistance in understanding multifaceted systems through showing the interrelationship (direct or indirect) between components, and the interrelationship of an action and reaction in terms of a cause and effect. Importantly, however, Shafique and Mahmood (2010) warn that care must be taken when using Models, as Models have the potential to invite overgeneralization since the Model is an abstraction of reality.

7.1.2 Foundation of the Operational Excellence Model for South African Pharmaceutical Manufacturing

Underpinned by the above-mentioned, Goes (2002) defines a conceptual Model as a representation of a system composed of a set of 'concepts' that are used to help people know, understand, or simulate the subject being represented. Naturally, therefore, the development process of this conceptual Model starts with an examination of theory. Following this, empirical data collection and data analysis operationalise theory. Observations about variables and causal relationships between the variables are recorded and evaluated in this chapter to determine priority, identify logical errors and check validity. The integration of theories and findings from the literature and that of data analysis ultimately provide this study with a summary which highlights concepts for inclusion in a conceptual Model for the South African pharmaceutical manufacturing industry.

7.1.3 Proposed Operational Excellence Model for South African Pharmaceutical Manufacturing

The conceptual Model developed by this study is called the SA Pharma OpEx Model. The primary concepts in this Model originate from Chapter Two, in which OpEx is explored from a quality management perspective. Chapter Two also reviews the most prominent dimensions of OpEx from the most internationally recognised quality awards. Strategy, Leadership, Systems Approach, Employee Empowerment, Continual Improvement, Customer Focus, Fact-based Management, Supplier Management and Training and Agility are accentuated as suitable dimensions for the SA Pharma OpEx Model.

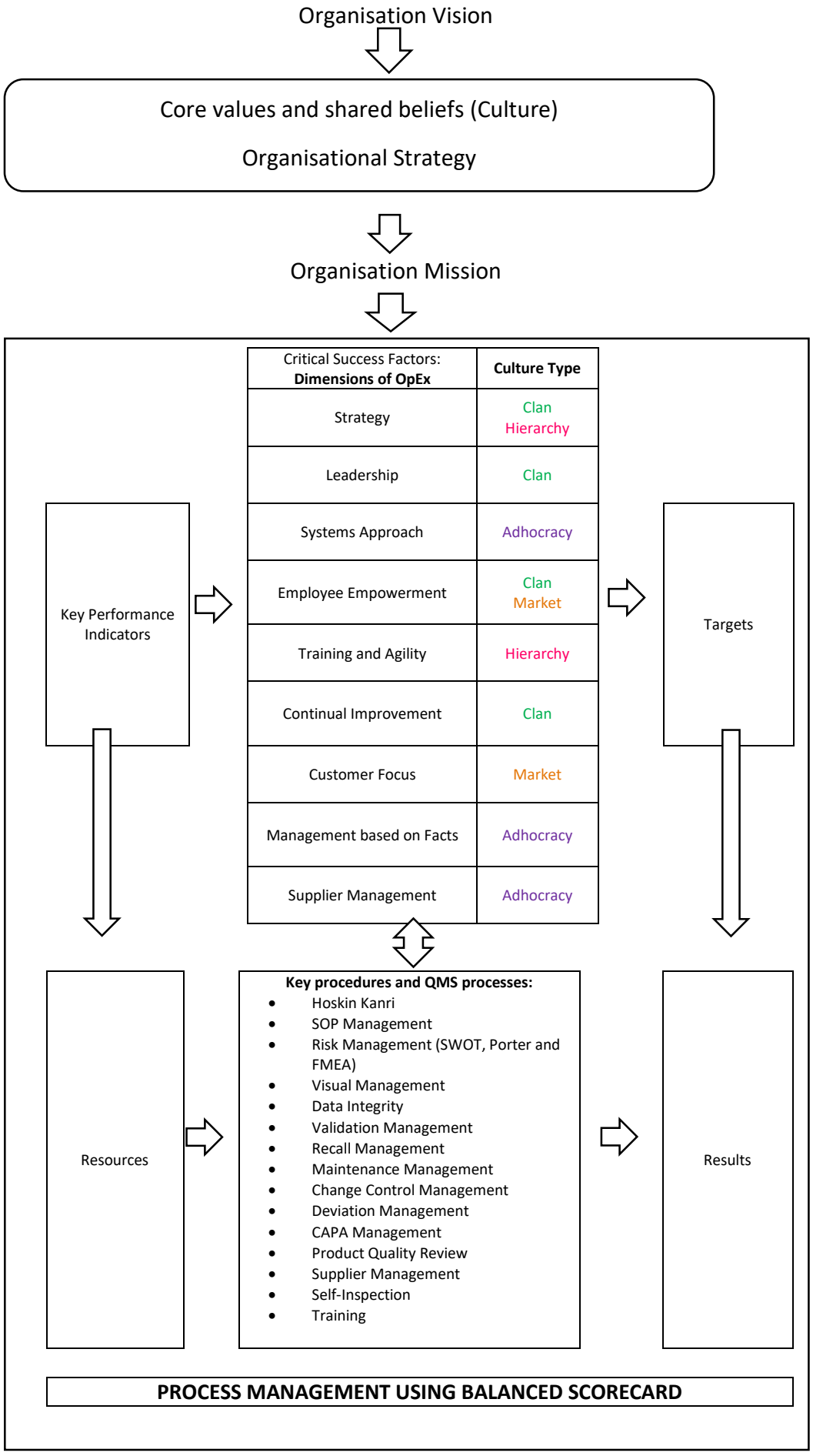
Chapter Two then probes the concept of Quality Culture and Climate as a subset of culture and suggests that the success of Quality Management Practices depends on Quality Culture. Fundamentally important and associated with this, data analysis presented in Chapter Six finds that the coefficient of determination (r^2) is 0.680, which substantiates the theory presented in Chapter Two. The interpretation of this is that 68% of any changes that take place in Quality Management Practices in pharmaceutical organisations in South Africa are due

to a change that takes place in Quality Culture, and the climate during the management of quality. This result is statistically significant.

Equally important, Chapter Two illuminates the competing values of culture. The literature on competing values typifies culture on the basis of two criteria, namely outward or inward focus and flexibility or rigidness. This sets a foundation and enables this study to develop a two-part questionnaire to assess the culture of South African pharmaceutical manufacturing organisations empirically. The analysis of data collected by this questionnaire yields findings on the individual culture types that support the above-mentioned individual OpEx dimensions. These findings are presented in Chapter Six. Specifically, the clan culture has the most explanatory power over Strategy, Leadership, Employee Empowerment and Continual Improvement; the adhocracy culture has the most explanatory power over Supplier partnership, Fact-Based Management and Systems Approach; the market culture has the most explanatory power over Employee Empowerment, and Customer Focus and hierarchical culture has the most explanatory power over Strategy and Training and Agility. Alignment is noted between this and the comparative study presented in Chapter Four, as Chapter Four concludes that a dichotomy and the balance of OCAI culture types are required in the pharmaceutical industry. Triangulation of all the aforementioned allows this study to start drafting the conceptual Model as depicted in Figure 7.1.

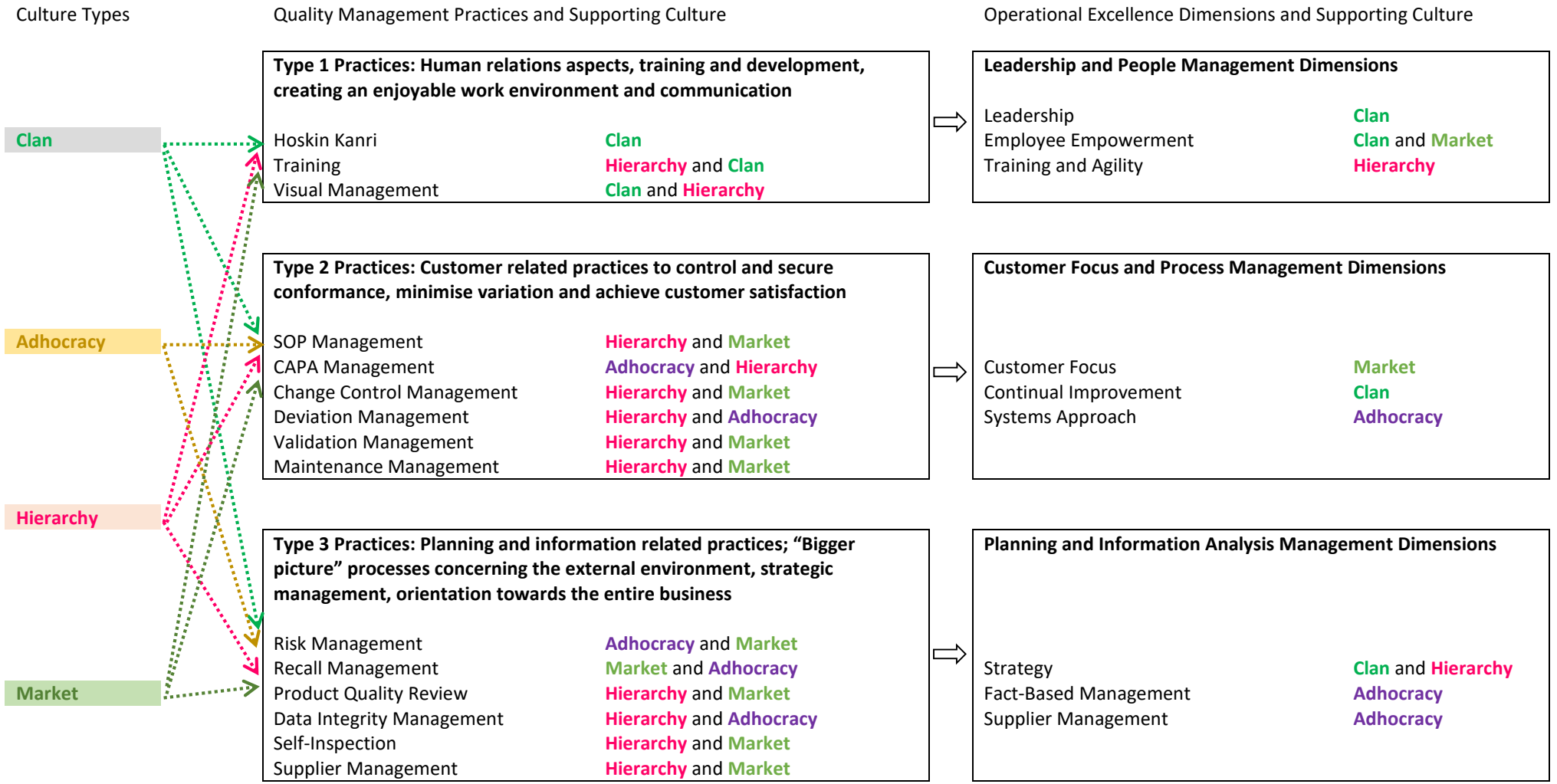
Moreover, literature in Chapter Three highlights selected Quality Management Practices, namely SOP management, Risk Management, Recall Management, Maintenance Management, Change Control Management, Deviation Management, CAPA Management, Product Quality Review, Supplier Management, Self-Inspection and Training as important due to GMP. The pilot study highlights additional practices namely Hoskin Kanri, Validation Management, Visual Management and Data Integrity Management. These practices are all included in the conceptual OpEx Model for the South African Pharmaceutical Industry.

Figure 7.1: Proposed SA Pharma OpEx Model Part One: Operational Excellence Dimensions (Developed by Researcher)



Revisiting the comparative study examined in Chapter Four, a blend of OCAI cultural attributes is required to support Quality Management Practices optimally in an OpEx endeavour. Therefore, the SA Pharma OpEx Model is expanded (see Figure 7.2) following the guidance of pluralist model approaches used by Gambi et al. (2013), Xu, Robbins and Fredendall, (2010) and Prajogo and McDermott, (2005). Their research approach involves categorising key Quality Management Practices into domains comparable to the OpEx dimensions of this research. Each of these studies identifies supporting culture types for selected Quality Management Practices or dimension. Thus, the proposed conceptual Model of SA Pharma OpEx model is represented by both Figure 7.1 and Figure 7.2 respectively. Figure 7.1 is part one of the Model, and Figure 7.2 is part two of the Model.

Figure 7.2: Proposed SA Pharma OpEx Model Part Two: Operational Excellence Dimensions, Quality Management Practices and supporting Culture Types (Developed by the Researcher)



7.2 Main study: Qualitative data analysis

The discussion of the main study qualitative data analysis which follows consists of three sections. First, the data collection and preparation process is described. Thereafter a descriptive qualitative analysis is presented on the structure of the proposed Model, the proposed dimensions and the proposed Quality Management Practices in the Model. The final section is a discussion on the relationship between OCAI culture types and Quality Management Practices and Dimensions in the proposed Model.

7.2.1 Data collection and preparation process

During this phase, qualitative data was collected and analysed to achieve the five aims of the qualitative phase as discussed in Chapter Five. These aims were achieved through an examination of the views of three purposely selected research participants (n=3). Participants were selected on the criteria of identification as experts in the industry and location in the three different geographically important cities in South Africa.

Each interview took place in a meeting room at the organisation where the research participant was employed at the time of the interview. Meeting rooms were booked in advance, and each interview lasted between 45 and 90 minutes. Before interviews commenced, the participants were presented with an introductory session in which they were given a diagram of both parts (part one and part two) of the SA Pharma OpEx Model. The rationale behind the research and the overarching aim of this study was explained to them. An explanation of the Model relative to the OCAI culture types was also provided. Participants were assured of the ethical standards that would be maintained throughout the study and that their right to privacy would be respected. The manner in which confidentiality and anonymity were going to be maintained throughout the research was explained.

Furthermore, the process in which data gathering and dissemination of results would be managed was also explained. Finally, they were invited to ask any questions or raise any issue that required clarification. After the introductory

session, each participant agreed to sign the informed consent, which was attached to the interview schedule. The content form can be seen on page 2 of the interview schedule which is attached as Annexure 7A.

During the interview process, the researcher made notes of key issues on an interview guide and used them to probe pertinent issues (Hennink, Hutter and Bailey, 2011) related to this study. Data saturation was a technique used by the Researcher during interviews. Questions were asked in various ways until no new information was provided from research participants. Immediately following each interview, the researcher transcribed the digitally recorded audio files to text and anonymised the transcripts. All the researcher notes that were made during the interview process were included in the transcripts. After transcription, the text documents were returned to interview participants who confirmed the accuracy of the transcripts. The transcripts were then coded by the researcher using ATLASti software.

This study uses thematic analysis to identify themes during qualitative data analysis. Bazeley (2017) suggests that the process of thematic analysis consists of two consecutive stages. The first stage involves data reduction by means of coding. Coding is the process of assigning descriptive code labels to sections of transcribed text. Each code fits into one or more conceptual code categories (also referred to as code families). The second stage involves the exploration of the relationships between the conceptual code categories. This exploration illuminates the themes which are related to the research problem and thereby enables this study to meet the final research objective.

As specified in Chapter Five, there were four code categories in this study. They are as follows: the structure of the Model, OpEx dimensions in the model, Quality Management Practices in the Model and Culture. The proceeding section starts by describing the first three code categories and thereafter explores the relationship between Quality Management Practices, OpEx dimensions and Culture.

7.2.2 Qualitative results: Descriptive analysis of the structure of the Model, Quality Dimensions and Quality Management Practices

A descriptive qualitative analysis is presented in the section that follows on the structure of the proposed conceptual OpEx Model. Thereafter, dimensions that are proposed for inclusion in the Model are discussed before a discussion on the Quality Management Practices that are proposed for the Model is presented.

7.2.2a Overarching structure of the Model

When participants provided their impressions of the structure of the proposed conceptual OpEx Model, they generally agreed that the overarching structure was adequate in terms of its ability to quickly communicate the overall intended message, which is that culture supports Quality Management Practices and that this leads to OpEx in a pharmaceutical manufacturing organisation. Participant B (from the Johannesburg based organisation) and Participant C (from the Durban based organisation) expressed particularly positive views regarding the alignment of quality strategy with an organisational strategy for success in the South African pharmaceutical industry. Participant C stated that "…[the model] *allows you to align your quality strategy with your governance strategy and brings it all together*".

Furthermore, in support of the goal of the proposed Model, which is to integrate overall business strategy with an organisation's quality strategy, Participant B shared a personal experience from a period when he worked at a different pharmaceutical organisation to the one where he was employed at the time that this research took place. That pharmaceutical organisation adopted an internal approach similar to that proposed by the conceptual OpEx Model of this study. He explained that the CEO of that organisation personally welcomed all new employees by sharing the organisation's core values and linking this to the quality strategy and business strategy. He believes that the aforementioned treatment of new employees resulted in a "*culture of performance*" in that organisation. This approach is notably consistent with the views of Lindsay and Evans (2017), Williams (2008) and van Donk and Sanders, (1993) on culture and performance as discussed in Chapter Two of this study.

Adding further support to the structure of the model, and in consideration of key performance indicators (KPIs) and resources that lead to targets and results, Participant B was very positive about KPIs and resources being included in the Model. He stated that "*This Model is fine. then what is driving all the KPIs here, is the targets. And you are having targets. And then here are the results, and there are the resources. This is good*". Participant B also implied that human capital is regarded as the most important resource in his organisation. Consistent with this idea, the importance of culture in the Model is promoted since culture is directly associated with human capital.

Participant A (from the Cape Town-based organisation) also articulated that she found the inclusion of the concept of targets useful in the conceptual OpEx Model. She explained that seeing the graphic depiction of the relationship between targets and activity in pharmaceutical organisations would assist an organisation with understanding how specific activities in an organisation, supported by culture, would lead to meeting targets. She noted, "*For me, this is useful to see how we get to our targets, so definitely all these dimensions, the culture types and the key procedures is good. And it is something that we could use. It's something that I feel that I could use – can be useful in industry*".

In considering Lindsay and Evans (2017); Kanji and Yui, (1997), this study gathers that, from a communication perspective, the conceptual OpEx Model is capable of assisting an organisation to effectively communicate the integral nature of quality objectives which reside in business objectives. This is exemplified by Participant A, who said, "*The Model needs to be diffused throughout the whole company, so everyone in all departments understands that we are all working together for the common purpose for the business objectives*".

She emphasised, *"It is not just production pushing sales, it's not just QA making sure that everyone is complying to guidelines, it is not just QC testing the product, not just RA doing what they are doing, it is everybody working together as a team. I can see the overview* (of the Model) *– as a tool – that can be useful to the organisation spread, not just within QA, but throughout the whole company*".

A final general consensus on the structure of the Model that emerged from all three participants is that they thought the Model would be particularly useful for a gap analysis in their respective organisations Extracts taken to support this are Participant B stating ,*"…remember that you can also use it as gap analysis* [tool]" and Participant A who said, "*For sure, yes definitely, yes it can be used for gap analysis – to see where we are strong in our strategy. Are we strong in our strategy? Are we a clan but are we strong in our strategy, our customer focus? What about our commitment to continual improvement? How we doing on training? So definitely it can be used to determine the gap.*"

A significant shortcoming of this conceptual Model that was highlighted by Participant C is that the Model lacks a financial component. He points out, "*We* (pharmaceutical organisations) *have to be commercially aligned…GMP requires you to have stock security and more secure supply of stock, so there has to be some factor here with some commercial* (component)*… there's some commercial piece missing here".* He argued that even though it might seem as if the quality department of an organisation does not have a direct sales function, and does not directly generate income for the organisation, the role of the quality department should not be regarded in isolation from the commercial part of the organisation. He added, "*Even though we are quality, and we would like to have a Quality Culture, we* (should be) *so much more focussed on steering the commercial business objectives".* From this, it is apparent that this study must acknowledge the importance of the financial component in the OpEx, even though this was excluded from the scope of this study, as outlined in Chapter One.

Ultimately, this research study deduced that the structure of the conceptual OpEx Model is suitable to meet the needs of the South African pharmaceutical industry. However, a financial component must be considered to ensure that it will be utilised by the South African pharmaceutical industry. The framework of the SA Pharma OpEx Model communicates its intended message and is easy to understand and follow. The next two sections interrogate the contents of the Model.

7.2.2b Dimensions of Operational Excellence

The analysis of data related to the dimensions of OpEx of the SA Pharma OpEx Model revealed that only a minor change to the proposed Model was required. During data collection, participants were asked to comment on each of the nine OpEx dimension depicted in Figure 7.1. They were also asked if they believed that a dimension was missing from the SA Pharma OpEx Model, or if any dimension present in the proposed Model was unnecessary. Finally, they were asked if they felt that the dimensions were adequately positioned into the three different OpEx categories, namely the Leadership and People Management Group, the Customer Focus and Process Management Group and the Planning and Information Analysis Management Group, as can be seen in Figure 7.2.

In general, all the participants agreed with the nine OpEx dimensions identified through literature. Participant A said that the dimensions were a "*reflection of the real world*". Participant C suggested that the dimension which measures employee empowerment be also expanded to measure employee engagement in an organisation. He argued that "*employee wellness*" is a critical aspect associated with employee performance because if employees do not feel that they are cared for, their performance will decrease, and it will also have a negative influence on the culture of an organisation. He explains that "…(when) *the moral is at an all-time low because the level of trust in the organisation is being eroded by the process, they not going to be meeting organisational mission and objectives".* He added, "*So those two things, a financial, as well as an employee engagement empowerment aspect there, those are my suggestions".* This relates to the argument presented by Shanley (2017a), Shanley (2017b) and Shanley (2017c) in Chapter Four, which highlights the importance of an OpEx strategy being relevant to the needs of business and the demands of customers to be successful. This study, therefore, deduced that a financial and an employee engagement aspect are vital in a conceptual OpEx Model for the South African pharmaceutical industry.

7.2.2c Quality Management Practices for Operational Excellence

Consistent with the requirements of GMP (Medicines Control Council 2010) as discussed in Chapter Three, all the research participants agree with the

suggested Quality Management Practices proposed for inclusion in the proposed Model. Participant A states that "*...everything that you've got there, I very much agree that that must be part of the key procedures"* and Participant C concedes that (there is) "*…some variance from this to that, but this is the norm, yes"*. All participants also mentioned the interdependence of individual Quality Management Practices which further corroborates the findings of Chapter Three. This study finds it interesting that, unlike Participant A and Participant C who do not believe that Quality Management Practices are used in a specific order, Participant B believes that there is particular order that should be followed when practices are used, as evident from the excerpt, "*…Training is the base in my case anyway, so it goes up… so Deviation, Change Control, CAPA, Product Quality Review, Supply Management, these are the day to day activities which we are doing, then Risk Management".* In essence, Participant B was the only participant who was of the opinion that in the day to day practice of a pharmaceutical organisation, employees of the organisation use quality management tools in a specified sequence.

Another interesting observation is that all three participants emphasised the importance of validation management in particular. Participant B explained that validation management is a form of "*de-risking the business"* and said that he personally provides regular training in his organisation on all aspects of validation management, to ensure that that production flows optimally.

A Quality Management Practice missing from the proposed Model, which was highlighted by both Participants B and C, is formalised Batch Release Management. Both participants stressed that without effective batch release management, a pharmaceutical organisation would never be able to be operationally excellent. Participant C explained that "*the process is deficient because we're not getting stock out of the warehouse, everybody is trained but the product is not released so there is no stock….So it's definitely important and missing from here"*. Both Participant B and C indicated that they had designated teams of pharmacists and pharmacists' assistants at their respective organisations to ensure a smooth flow of quality assured stock being released into the market.

Another noteworthy change to the proposed Model suggested by Participant B is that the Quality Management Practice Recall Management, which forms part of the Planning and Information Analysis Group in the proposed Model, would be better suited in the Customer Focus and Process Management Group of OpEx dimensions. He explains that "*A recall process is reactional. It belongs in the type 2* (refers to Customer Focus and Process Management) *group*". Participant C expressed a similar view on recall management by stating that "*You have the facts, you respond to the facts and there is a very firm set procedure that you have to follow, laid out by your own process as well as by the regulator".* Additional insight on this matter was provided by Participant B who pointed out the distinction between Recall Management and a Mock Recall Process. In accordance with GMP, a Mock Recall Process needs to take place at least once a year (Medicines Control Council 2010), which would put an organisation in a position to explore different options when recalling stock. Participant C explains that, when an organisation is forced to initiate a live recall process, "*there is very little latitude with what you say, being creative, innovative, entrepreneurial and visionary*". Both participants expressed a strong view that recall management is an operational Quality Management Practice. In light of this observation it was decided to move the Recall Management practice to the Customer Focus and Process Management Group of OpEx dimensions, and also to include a new practice (called a Mock Recall Management practice) to the Planning and Information Analysis Management Group.

The descriptive analysis above provides this study with the information necessary to improve the structure for the SA Pharma OpEx Model and thereby optimise the Model for the South African pharmaceutical industry. The next section discusses the relationship between quality management and culture that influences quality management.

7.2.3 Qualitative Results: Relationship between Quality Management and Culture

The use of ATLASti software enables this study to perform a thematic analysis and construct network diagrams of themes, to more fully understand the

relationship between quality management and culture. As mentioned earlier in this chapter and outlined by the research design described in Chapter Five, the final empirical phase of this study sets out to determine the relationship between the OCAI culture types and Quality Management Practice, as well as each OpEx dimension group and each OpEx dimension during the management of quality in selected South African pharmaceutical organisations. This section concludes with a summary of the extent to which culture is believed to have an impact on operations in South African pharmaceutical organisations and suggests the reasons for the impact, based on the views of the research participants.

7.2.3a Relationship between OCAI culture types and Quality Management Practices

The research participants approved all the OCAI culture types that were proposed as supporting culture types for the Quality Management Practices depicted by the Model, with the exception of Supplier Management. With regard to this, Participant B and Participant C said that they believe that Supplier Management supported the hierarchy culture type and not adhocracy type as proposed. Participant C noted that even the clan culture (for Supplier Development) would be more suitable than adhocracy. He said that "*I'd have suspected it is more hierarchical …or more collaborative* (rather) *than being creative. I am not aligned with that. I don't see it. I would have expected to see more clan there… team collaboration rather than the adhocracy descriptors that you have there*".

While all three participants did not expressly disagree with training being supported by the hierarchy culture type (due to the highly regulated nature of the pharmaceutical industry), they all mentioned that they were surprised that training was not supported by the clan culture type. Furthermore, Participant C said that he was also surprised that employee empowerment was empirically linked to the market-driven culture. Upon further consideration, he suggested that, because employees in the same organisation compete against each other in terms of KPIs and performance incentives, this could explain the empirical finding which emerged from quantitative data analysis.

7.2.3b Relationship between OCAI culture types and OpEx dimensions

The three research participants were all in agreement that shared values in their respective organisations constitute a measure of culture.

Furthermore, during each of the three interviews, each participant indicated strongly that culture influences the operational performance of an organisation, which is also consistent with Chapter Two of this study. This is exemplified by Participant C's statement that "*Culture for me is one of the hardest things to get right and if you have a gauge on what you need to concentrate on each level* (refers to culture)*, I think it will give us a useful tool to actually say, well this part of your business is what you actually need to concentrate on* (for optimal performance)*… This is an eye-opener for me that we need to approach it differently"*.

The research participants were particularly vocal on how clan culture supports the Leadership and People Management Dimensions. Excerpts taken from interview transcripts to support this are Participant C who said, "*It's good to see that the clan is sitting here on top with type 1 practices because it's just so important",* and Participant A who said that, "*Ok so I can see that, Hoskin Kanri with clan, …that's visible leadership. And training with clan, I can see training with clan definitely, firstly going together with your visible leadership that you have to on the floor, you have to be there, you have to be mentoring, nurturing and that's part of training. And I can see how visual management would be part of that to sustain effective operations".* Consistent with the views of Lindsay and Evans, (2017), Knapp, (2010) and Prajogo and McDermott, (2005), this study deduces that the clan culture is the foundation to sustaining effective quality management in an organisation. Furthermore, the clan culture must be driven by the leadership in the organisation.

Foregrounded by Chapter Three of this study, features of the hierarchical culture type are not only mandatory but also support optimal functioning of operations in pharmaceutical manufacturing. Participant A sums up the critical importance of hierarchy by saying that "*there are many pharmaceutical guidelines and one of it is the PIC/S guideline that our country and our SAHPRA which was previously*

MCC, have adopted as their baseline document. With these guidelines out there a lot of the requirements are prescribed basically, even though it is called a guideline, it is prescribed to you…" and *"…our inspectorate is always looking for evidence"*. Participant B draws attention to the consequences of not following hierarchical procedures by stating, *"So what I'm saying is if you don't follow the rules we will pick up that you didn't follow the rules"*. By this, he implies that audits and self-inspection are integral practices and serve as a control measure to ensure that the correct procedures are followed. It is noteworthy that, immediately after making that statement, he points out the features of the clan culture that scaffold adherence to the inherently hierarchical nature of pharmaceutical organisations. He offers: "*But now mostly what is very important* (to follow the organisation's rules) *is, before the people come in, we need to train them. And if you check here, you see* (points to clan culture on the page). *So* (that is) *what we do* (at our organisation). *…I am talking about empowering"*. This finding highlights the symbiotic nature of different culture type traits in pharmaceutical organisations. To achieve success in OpEx dimensions, characteristic elements of different culture types must support each other. Participant C captures this sentiment when he reviews the decision-making process in a pharmaceutical organisation by saying that "*it'll be a combination of distilling information we gathered from the clan and putting it together from a hierarchy perspective.*"

Similarly, highlighting the joint importance of the adhocracy and market-driven culture traits when discussing the Fact-Based Management OpEx dimension, Participant C says that, *"If you are going to be relevant in three or four years' time or ten years' time then you have to be willing to change based on the information that's coming your way. Otherwise, you'll become another KODAK. If you are not managing and responding based on innovation and different ways of thinking, entrepreneurial, visionary, then you are going to be out-dated and left behind*". With this statement, the research participant foregrounds the importance of continual improvement and adaptability to stay relative and competitive in the marketplace. This statement also highlights the symbiotic nature of culture types.

It is noteworthy that Participant B also pointed out that a combination of culture type traits is needed for optimal functioning of the organisation. He says that "*we need to be visionary and get new resource for effectiveness, for planning. But* (for) *the strategy, we need clan and hierarchy. … Customer focus is market, yes? Continual improvement is adhocracy, yes it's supposed to be clan because yes you see it can be clan, continual improvement or it can be adhocracy because continual improvement you need some entrepreneur skills and innovative skills".* When asked about the blend of cultures research Participant B suggested that "*clan and hierarchy are the most, and adhocracy and market not such a big percentage 15, 15, 35, 35*". This study notes that the view of this research participant is similar to the findings of data analysis in Chapter Six. The result of this study finds the overall average percentage in all South African pharmaceutical manufacturing organisations as follows: the hierarchical culture is 33%, the clan culture is 27%, the adhocracy culture is 15%, and the market-driven culture is 25%.

The argument for variety and balance in culture types was further advanced by Participant C, who openly questioned if the Customer Focus and Process Management Group of OpEx dimensions practices are predominantly hierarchical, as indicated in the proposed Model. He conveyed the belief that they should be more market-driven while simultaneously being supported by the clan culture type traits. He said: "*What sticks out for me is all this hierarchy that is sitting here, I'm surprised by that. Yes, it's balanced by market focus, which is what I said to you early on, but we as a company are becoming a quality team that is commission focused. I think it validates what is happening in my own team – this market and commercial focus. Hierarchical, I suppose and I'm not surprised because we are working in a GMP environment, but I would have liked to have seen – just because we don't; want to be so structurally bound, it's good to see that clan is sitting here on top with type 1 because that is so important*".

Equally significant to this study is Participant C's suggestion that the Model be further developed to keep track of the prevalence of culture types in organisations, as a form of KPIs. He believes that this would add tremendous value to South African pharmaceutical organisations who strive for OpEx. He

states: "*You know that on our performance we track, you know that we are tracking all our metrics, but it doesn't actually measure anything on these metrics* (points to culture). *So this is a different set of metrics. We have performance KPIs, but not necessarily culture KPIs. This may actually enable your performance KPIs"* This is regarded as particularly significant because the research participant was not aware (he was not told) of the quantitative outcome, which is that quality management is a dependent variable of Quality Culture. However, his view supports these finding from Chapter Six.

7.2.3c Deductions on Culture and Quality Management that are derived from qualitative data analysis

Quality Culture is an underlying and understated tenet in South African pharmaceutical manufacturing organisations. Quality Culture is the shared values maintained by employees of the organisation pertaining to the management of quality. The OCAI culture types give this research a lens through which to examine this culture.

From data analysis above, this study deduces that a variety and balance of OCAI culture type traits are required to effectively promote and support OpEx in the South African pharmaceutical industry. Hierarchical culture traits are essential for compliance with GMP, as pointed out by Participant A since organisations that do not follow the strict rules and procedures that are mandated by GMP will not be able to trade in South Africa.

Participant C foregrounded that clan culture type traits are vital to sustain quality management gains and thereby ensure continuous compliance with GMP. He argues that, if employees feel valued, they will perform their functions very well. He explains that "*employee wellness*" is a critical aspect associated with employee performance because, if employees do not feel that they are cared for, their performance will decrease.

Finally, this research deduces that adhocracy and market-driven culture traits are also critical features that South African pharmaceutical organisations require for continual improvement and global competitiveness. Examples were cited by all three research participants interviewed by this study. Participant A, however,

captures this sentiment by declaring that "…w*hether they like it or not they are competing*. *Companies are looking at what competitors are doing, and thinking how can we get our product to market first, how can we improve and how can we protect what we develop. Companies go to great lengths to protect intellectual property through patents*".

This study concludes that a balance of these four culture types is needed for OpEx and accordingly a balanced scorecard is also deemed an appropriate mechanism to deploy the conceptual OpEx Model. The specific structure and composition of the balanced scorecard fall outside the scope of this research study; however, the concept of a balanced scorecard is supported by Participant C who states: "*I think the balanced scorecard approach is correct – I would like to see what the balanced scorecard looks like before saying yes"*. This implies that the selection of items measured by the balanced scorecard is consequential. He explains this by stating that "*The balanced scorecard can't just be performance against how many deviations you received and how quickly you closed them out, but also how to measure some type of, quality of culture, and then year on year, every six months* (one asks) *How is that changing and how is your performance changing?*". This study regards this as further evidence that confirms the nature of the correlation between a culture shift and performance shift.

7.3 Limitations and Model optimisation

A limitation of the Model is that is has been developed specifically for South African organisations. It must be noted that, although an attempt was made to secure a census sample, the response rate for the questionnaire was 57%. In addition, qualitative data were obtained from three purposely selected respondents. The research was designed to ensure that as far as possible, it is representative of South African pharmaceutical organisations; however, the researcher acknowledges that this research might not be transferrable to all pharmaceutical organisations in South Africa.

A further limitation is that the coefficient of determination (r^2) of the Model developed by this study is 0.680. This means that 68% of any changes that take place in Quality Management Practices in pharmaceutical organisations in South Africa are due to a change that takes place in Quality Culture and the climate during the management of quality. However, the remaining 32% of the changes are due to unknown variables that have not necessarily been considered by this study.

A limitation associated with the output of this study, as highlighted by the research participants in the qualitative phase of this study, is that this Model lacks a financial component. This study also does not provide guidance on how the Model should be deployed within an organisation. This is the first time that a study on the impact of Quality Culture in the South African pharmaceutical industry has taken place, and this study has hopefully set the stage for future research. It is hoped that any further research would rigorously test and interrogate the findings of this study, expand on the conceptual OpEx Model and investigate deployment.

Notwithstanding the limitations above, all the conclusions derived from the qualitative analysis presented in this chapter enable this study to modify and propose an optimised conceptual OpEx Model (part one and part two) for South African pharmaceutical organisations to use. This Model is called the Final SA Pharma OpEx Model and is depicted by Figure 7.3 (part one) and Figure 7.4 (part two) as follows:

Figure 7.3 Final SA Pharma OpEx Model Part One: Operational Excellence Dimensions

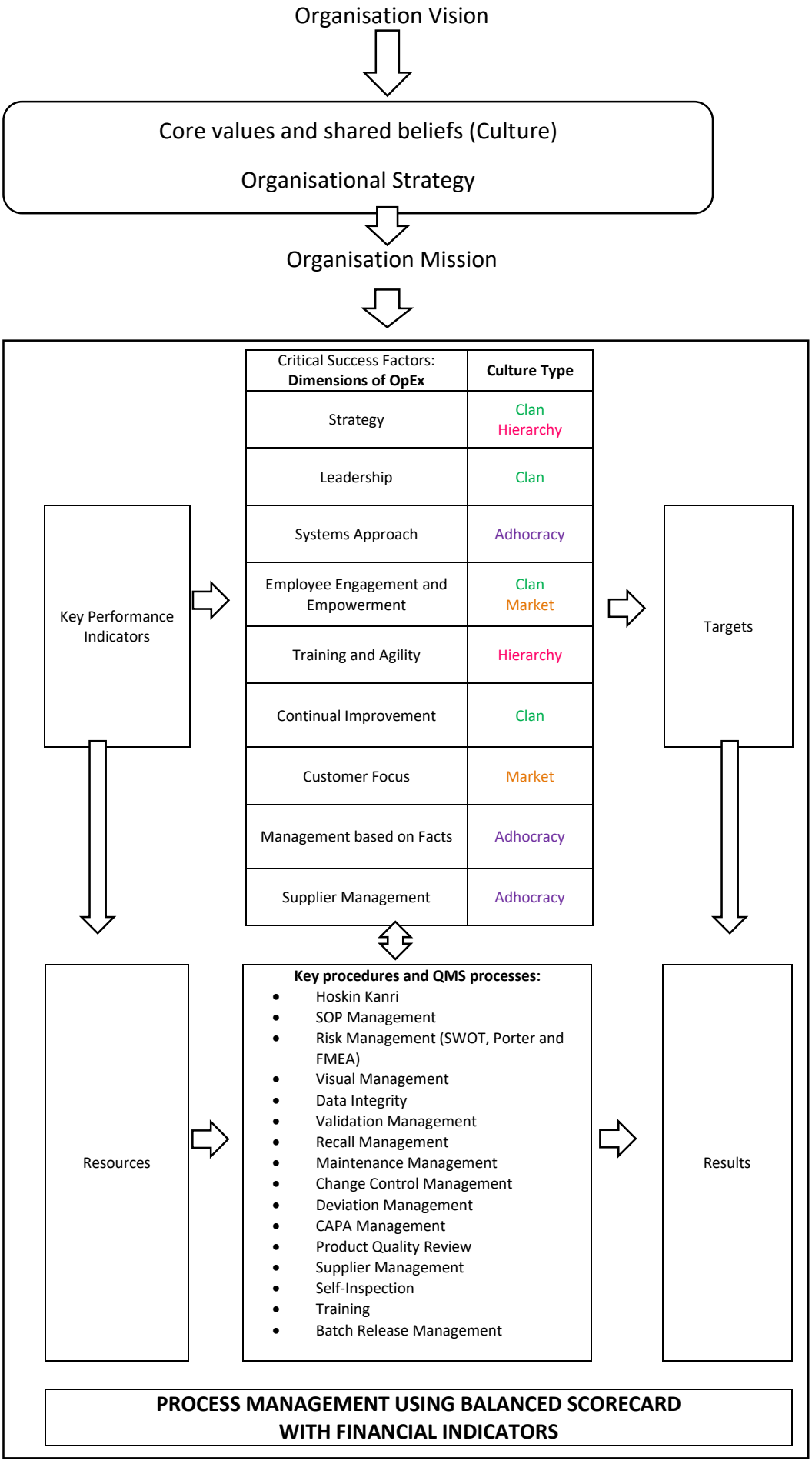
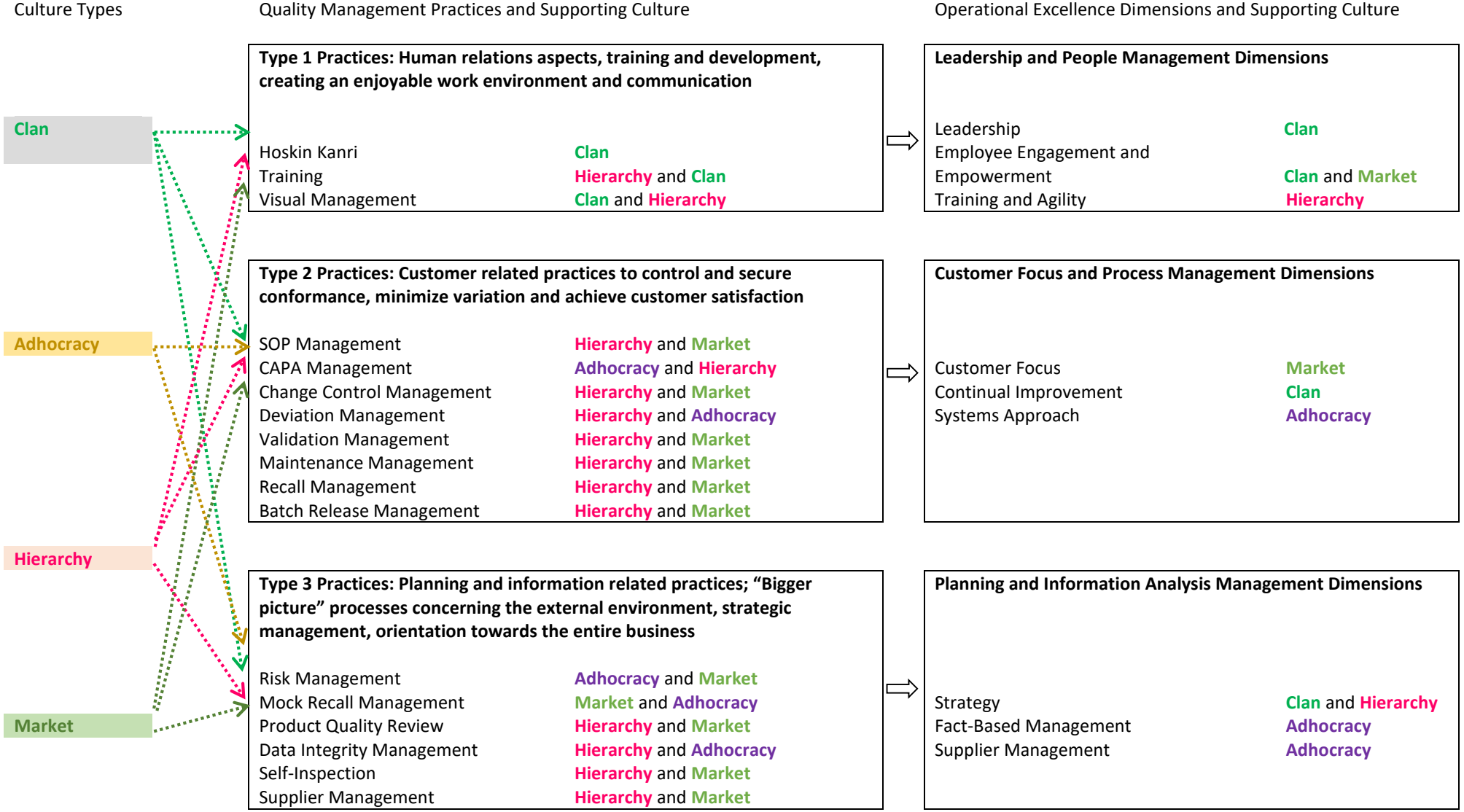


Figure 7.4 Final SA Pharma OpEx Model Part Two: Operational Excellence Dimensions, Quality Management Practices and supporting Culture Types



7.4 Chapter summary

This chapter consolidates the findings of the literature review and quantitative data analysis presented in Chapter Six, in order to develop a proposed Model, which was then empirically explored through a qualitative method. The structure of the Model and the concepts in the Model, namely the OpEx dimensions and Quality Management Practices included in the Model, were interrogated. Thereafter the relationship between Quality Culture and Quality Management Practices was examined through an OCAI culture type lens. The findings of this qualitative examination enable the optimisation of the final SA Pharma Opex Model, which was presented as Figure 7.3 and Figure 7.4. Limitations of the Model were acknowledged, and recommendations for future studies were given.

In the next chapter, the conclusion of this research is presented, and recommendations stemming from this research study will be addressed.

CHAPTER EIGHT
CONCLUSION AND RECOMMENDATIONS

'Learning is not compulsory, ...neither is survival.'

- Dr William Edward Deming

This research study set out to investigate the effect of Quality Culture on Quality Management Practices in pharmaceutical manufacturing organisations, with the intention of using this knowledge to design a conceptual OpEx Model for South African organisations. The outcome of this study, namely the SA Pharma OpEx Model, is a tool meant to assist all pharmaceutical organisations to improve the quality of their manufacturing operations, with the proposal that it is capable of elevating OpEx in the South African pharmaceutical industry in general. Thereby, the outcome of this research addresses the legacy of historical inequality in the South African pharmaceutical industry, as highlighted in Chapter One of this study. The purpose of this final chapter is to provide a conclusive summary of all the key findings related to each of the research objectives, as indicated in Chapter One and thereafter operationalised in the succeeding chapters of this thesis. This chapter concludes with recommendations for future research and a chapter summary.

8.1 The research problem and objectives revisited

The research problem that was presented in Chapter One is: "The dearth of knowledge on the impact of Quality Culture inhibits South African pharmaceutical manufacturing organisations from selecting the most suitable Quality Management Practices for inclusion in a conceptual OpEx Model". Thus, in an endeavour to address this problem this study sets out to accomplish five objectives. The proceeding section presents a brief synopsis of how the chapters of this study accomplished the research objectives.

8.1.1 Objective One and Objective Two revisited

Objective One and Two were simultaneously accomplished by Chapter Two and Three. The first two research objectives were:

- Identify the most common Quality Management Practices to support business performance and regulatory requirements in the pharmaceutical industry through the evaluation of literature.
- Conduct an explorative literature study on OpEx strategies used in the global pharmaceutical industry.

Conclusion and recommendation

As a standalone chapter, Chapter Two did not meet any of the research objectives. However, Chapter Two set the vital foundation on which all succeeding chapters are developed since it establishes the important theoretical link between the concept of Quality Culture and Quality Climate (as a subset of Quality Culture) with the success of quality management in an organisation. Chapter Two concluded that OpEx is essential for commercial success in the pharmaceutical industry (Coffey 2008) and that culture is key to OpEx (Malhi 2013). Culture increases employee commitment and loyalty, due to personal and emotional attachment to values. Values drive employee behaviour which, in turn, drives excellence. Thereafter the chapter explored the measurement of 'excellence' in operations, through the comparison of the three most widely known international quality awards. Ultimately this chapter yielded practical dimensions of OpEx for consideration and inclusion in the Model.

Chapter Three provided the historical context around the origins of regulation in the global pharmaceutical industry and presented justifications for the promulgation of GMP. The most common global Quality Management Practices required to comply with GMP were highlighted, and the interdependent nature of Quality Management Practices in the pharmaceutical industry was emphasised. Strategy is defined as the general approach that an organisation will follow in order to achieve its goals (Cooper and Schindler, 2014) and this chapter explored various quality management strategies aligned with GMP in order to drive the progress of quality and simultaneously achieve operational and business success. Thereby Chapter Two and Chapter Three meet the first research objective, which is to identify the most common Quality Management Practices to support business performance and regulatory requirements in the

pharmaceutical industry, through the evaluation of literature and the second research objective, which is to conduct an explorative literature study on OpEx strategies used in the global pharmaceutical industry. Dimensions of OpEx identified in Chapter Two and selected Quality Management Practices identified in Chapter Three were recommended for inclusion for inclusion in the conceptual OpEx Model developed in Chapter Seven.

8.1.2 Objective Three revisited

Objective Three of this study was accomplished by Chapter Four. Objective Three of this study is:

- Perform a literature examination on three founder member regulatory authorities of the ICH namely, Japan, Europe and the United States.

Conclusion and recommendation

Chapter Four examined the role of the four OCAI culture types in pharmaceutical manufacturing in the three founder member ICH regions. The findings of this comparative study are strongly associated with the findings of Chapter Two, which is that culture directs the behaviour of people. Culture is an unseen control mechanism for the daily routines and execution of operational tasks and this chapter also draws attention to the variety and balance of OCAI culture types that support continual improvement and development in the pharmaceutical industry. Thereby this chapter achieved the third research objective, which is to perform a literature examination on three founder member regulatory authorities of the ICH namely, Japan, Europe and the United States. Chapter Four concluded that a dichotomy and the balance of OCAI culture types are required in the pharmaceutical industry and a recommendation derived from this chapter was that OCAI culture types be considered during the development of a conceptual OpEx Model for the South African pharmaceutical industry.

8.1.3 Objective Four revisited

Objective Four of this study was accomplished by Chapter Six. Objective Four of this study is:

- Conduct a focused study on Quality Management Practices, based on data collected from selected manufacturers of Category A medicines in the pharmaceutical industry in South Africa.

Conclusion and recommendation

The most fundamentally important finding from quantitative data analysis, as presented in Chapter Six, is that 68% of any changes that take place in Quality Management Practices in pharmaceutical organisations in South Africa are due to a change that takes place in Quality Culture and Climate during the management of quality. This statistically significant finding provides a foundation for further empirical studies. Chapter Six concluded that, in the South African pharmaceutical industry, the clan culture has the most explanatory power over Strategy, Leadership, Employee Empowerment and Continual Improvement; the adhocracy culture has the most explanatory power over Supplier Partnership, Fact-Based Management and Systems Approach; the market culture has the most explanatory power over Employee Empowerment, and Customer Focus and hierarchical culture has the most explanatory power over Strategy and Training and Agility.

Thereby Chapter Six achieved the fourth research objective, which was to conduct a focused study on Quality Management Practices, based on data collected from selected manufacturers of Category A medicines in the pharmaceutical industry in South Africa. This study regards it as noteworthy that alignment is noted between Chapter Six and the comparative study presented in Chapter Four, as Chapter Four concluded that a dichotomy and the balance of OCAI culture types are required in the pharmaceutical industry.

8.1.4 Objective Five revisited

Objective Five of this study was accomplished by Chapter Seven. Objective Five of this study is:

- Develop a conceptual Model of Quality Management Practices supported by Quality Culture for Category A manufacturers in the South African

Pharmaceutical Industry that promotes OpEx in alignment with the MCC (2010) Guide to GMP.

Conclusion and recommendation

Chapter Seven presented the findings of qualitative data analysis from three purposively selected research participants. This was the last stage of research required by this study in order to develop the SA Pharma OpEx Model. This chapter examined the value of specific Quality Management Practices, as well as the OpEx dimensions that are required by South African pharmaceutical manufacturers in particular. This analysis ultimately yielded the final Model depicted in Figure 7.3 and Figure 7.4 respectively.

Chapter Seven verified the agreement of the three research participants, namely that shared values in their respective organisations constitute a measure of culture and that culture facilitates the successful execution of Quality Management Practices. Further deductions chapter are that a balance of the OCAI culture types is needed for OpEx and that a balanced scorecard is an appropriate mechanism for deploying the conceptual OpEx Model. In addition, Chapter Seven also established that this Model would be useful for a gap analysis in their respective organisations.

Of particular importance is that derived from the views of the research participants, Chapter Seven concludes that the overall structure of the Model is good. From a communication perspective, this Model is capable of assisting an organisation to effectively communicate the integral nature of quality objectives which reside in business objectives. When the vision of an organisation is aligned with the culture of that organisation, the culture becomes a weapon to operationalise strategy and thereby achieve the mission of the organisation. KPIs lead to targets and resources lead to results. Chapter Seven thus achieved the fifth research objective of this study, which was to develop a Model of Quality Management Practices supported by Quality Culture for Category A manufacturers in the South African Pharmaceutical Industry. This chapter recommends that the SA Pharma OpEx Model be adopted by South African

pharmaceutical manufacturing organisations to improve their manufacturing operations.

8.2 Final conclusion drawn from key research findings

This research set out to provide South African pharmaceutical organisations with a quality tool which will enable them to elevate their global status in terms of quality management and manufacturing excellence. The SA Pharma OpEx Model is the end result of this research, and it showcases how awareness of the Quality Culture is of vital importance in pharmaceutical organisations. This is because culture can be harnessed to improve efforts to manage quality in South African pharmaceutical organisations, thereby improving operational performance. Specifically, in terms of the OCAI culture traits, hierarchical culture traits in the pharmaceutical industry are essential for compliance with GMP. Clan culture type traits are also vital in the industry to sustain quality management gains. Furthermore, adhocracy and market-driven culture traits are also critical features that South African pharmaceutical organisations require for continual improvement and global competitiveness. A pharmaceutical organisation with a Quality Culture which includes all these traits will be able to successfully manage their performance and be successful in all the dimensions of OpEx, as indicated in the SA Pharma OpEx Model. Therefore, on the basis of the literature reviewed and the empirical findings, this study concludes that culture influences quality management and successful quality management improves operational performance.

The ultimate objective of this research, to develop a conceptual Model of pharmaceutical manufacturing practices underpinned by Quality Culture that promotes OpEx in South African pharmaceutical organisations, in alignment with the Medicines Control Council (2010) Guide to GMP for a South African context, has, therefore, been met. Furthermore, the research problem of this study, which is “The dearth of knowledge on the impact of Quality Culture, inhibits South African pharmaceutical manufacturing organisations from selecting the most suitable Quality Management Practices for inclusion in a conceptual OpEx Model” has also been solved.

8.3 Recommendations for future research

During the development of the SA Pharma OpEx Model, findings from an empirical data analysis revealed that certain changes should be made to the Quality Management Practices that were originally proposed in the initial draft of the Model. These changes were the inclusion of batch release management to the Customer Focus and Process Management group of Quality Management Practices and Mock Recall Management to the Planning and Information Analysis group of Quality Management Practices. Furthermore, recall management was removed from the Planning and Information Analysis group of Quality Management Practices and placed in the Customer Focus and Process Management group of Quality Management Practices. The final change that was made by this study to the proposed SA Pharma OpEx Model was that the employee empowerment practice was expanded to include employee engagement. It is recommended that these changes be empirically examined by future studies.

Notwithstanding the aforementioned changes that were incorporated into the final version of the SA Pharma OpEx Model, this research study acknowledges that a limitation of the SA Pharma OpEx Model is that it lacks a financial component. The focus of this study was to examine OpEx from an operations perspective rather than a finance perspective. This study has however deduced that a balanced scorecard can be used to incorporate a financial aspect. The specific structure and composition of the balanced scorecard fall outside of the scope of this research study; and therefore, this study also recommends that this be empirically explored by future studies. This study recommends that a designated investigation be performed specifically for South African pharmaceutical organisations which take into consideration all the different financial structures that are present in South African pharmaceutical organisations.

As this is the first time that a study on the impact of Quality Culture in South African pharmaceutical industry took place, this study has set the stage for future research to rigorously test and interrogate the findings of this study, expand on

the SA Pharma OpEx Model and investigate organisational approaches to deploy the Model.

8.4 Concluding Remarks

OpEx is not an accidental occurrence. It is the result of purposeful design. This study deduces that OpEx is only sustainable if the Quality Culture in an organisation supports the Quality Management Strategy of that organisation. Since every strategy depends on human participation, this study also concludes that the Quality Culture of an organisation should not be ignored. Quality Culture represents the key to excellence.

Thus, to be operationally excellent, South African pharmaceutical organisations must determine their organisational values and adopt a quality strategy within an organisational strategy that is aligned to these values, to successfully fulfil their mission. By ensuring that their Quality Culture (shared values) is aligned to their strategy, organisations can meet their quality objectives and remain commercially viable with the least amount of effort. The Model developed by this research study is a tool that would enable companies to achieve this.

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Annexure 5A Linkages between original construct variables and reconstructed questionnaire constructs

Construct ID	Research Variable ID
Quality Management Practices	QMP1 - Overall perception of quality in organisation QMP2 - Organisational importance on following quality prescriptions QMP3 - Training on basic quality tools QMP4 - Employees share responsibility of equipment to ensure good quality QMP5 - Risk management is an attribute QMP6 - Planning and project management part of quality QMP7 - Waste reduction characterises organisation QMP8 - Value of incoming inspection QMP9 - Standardised supplier management QMP10 – Uniformity promotes quality
Quality Culture	QC1 – Shared mindset and set of values QC2 - Customer satisfaction is priority QC3 - Quality and cross-functional training in organisation QC4 - All employees understand what 'quality work' is QC5 - Organisational activities monitored to manage quality QC6 - Quality is superordinate value in organisation QC7 - Internal customer respected QC8 - Feedback loop to improve system QC9 - Each person knows what their contribution and fulfils it and will handle implications QC10 - Supplier collaboration
Quality Climate	OC1 - Aligned quality and business strategy OC2 – Sales overrides quality OC3 - Organisation-wide responsiveness to quality OC4 - Organisational agility: Quality requirements OC5 - Risk management in decision making OC6 - Innovation promotes continuous improvement OC7 - External customer/stakeholder satisfaction important OC8 – Innovation due to market requirements OC9 – Innovation due to R&D OC10 – Innovation due to quality requirements

Research Variable ID in new group	Reconstructed ID
QMP 6 QMP10 QC2	Leadership
QMP1 QC6 OC2	Strategy
QC1 QC8 OC3	Systems Approach
QMP2 QC7 OC7	Customer Focus
QMP7 OC6	Continual Improvement
QC4 QC9 QMP4	Employee Empowerment
QC5 QMP5 OC5	Fact-Based Management
QC10 QMP8 QMP9	Supplier Partnership
QC3 QMP3 OC 3 OC 4	Training and Agility

Annexure 5B: Plummer's Sources of Bias

Source 1: Informant (Participant) bias

1. Has unintended misinformation been given that the Researcher is aware of?
2. Has the Researcher noticed that a question/s was evaded?
3. Is there any evidence of direct lying or deception?
4. Does it appear to the Researcher as if the Participant is trying to present a false front or impression?
5. What may the Participant take for granted and thus not reveal?
6. How far is the Participant seeking to please the interviewer?
7. How much has been forgotten or overlooked by the Participant?

Source 2: Researcher bias

Could any of the following be shaping the outcome:

1. Attitudes of Researcher; age, gender, class, race, and so on?
2. Presentation of Researcher; dress, speech, body language?
3. Personality of Researcher: anxiety, need for approval, hostility, warmth, and so on?
4. Attitudes of Researcher: religion, politics, tolerance, general assumptions?
5. Scientific role of Researcher: theory held, and so on (Researcher expectations)

Source 3: Bias from interaction between Participant and Researcher

The joint act needs to be examined. Is bias coming from:

1. The physical setting - social space?
2. Any previous encounters or interaction?
3. Reactions to non-verbal communication?
4. Reactions to vocal (verbal) behaviour?

Annexure 6A Questionnaire Part 1 and Part 2

Part 1 Page 1 of 4

Faculty of Management Sciences
Department of Public Management & Economics

Dear Pharmaceutical Manufacturer
Please take some time (approximately 20 minutes) to complete this questionnaire. Your responses are very valuable and will provide important information that will contribute to the development of a conceptual model to achieve Operational Excellence (OpEx) in pharmaceutical manufacturing organisations. Once this study is complete, this model will be available for your organisation to use, if you wish to do so. **This questionnaire does not request any sensitive organisational information.**

You are under no obligation to complete this questionnaire; however, your participation will ensure that the requirements of your organisation are met by OpEx model being developed**. All information will be kept strictly confidential. The researcher will sign a confidentiality agreement.**

TITLE OF THE STUDY AND RESEARCHER DETAILS:

An analysis of quality culture and quality management practices in selected South African pharmaceutical organisations

By researcher: Bronwyn Claudia Swartz
Department of Industrial and Systems Engineering
CPUT Bellville Campus

Supervisor: Dr Shalini Singh

Purpose of the Questionnaire
OpEx strategies are a widely recognised tool, which many global pharmaceutical organisations have attempted to implement, with various degrees of success in an attempt to improve performance. This research evaluates the belief that the culture and climate of an organisation has a significant influence on the success of quality management practices in that organisation.

There are four sections to this questionnaire

Section A – Non-personal organisational details helps the researcher ensure that the study is representative.
Section B – Establishes the baseline quality culture of the organisation.
Section C – Evaluates current quality management practices in your organisation.
Section D – Evaluates the current organisational climate.

Thank you for your participation

Section A Non-personal organisational details to ensure representivity

A1 What is the name of the organisation you work for?

_____

A2 What is the job title or the current position/level that you fill at the organisation?

_____

Please rate short statements on an ordinal scale ranging from 1 to 7.

Annexure 6A Questionnaire Part 1 and Part 2 continued

Part 1 Page 2 of 4

Section B Quality management practices

QMP1 The overall perception of quality management in our organisation.

Negative	1	2	3	4	5	6	7	Positive

QMP2 The degree of importance attributed to always following prescribed quality management practices in our organisation.

Little importance	1	2	3	4	5	6	7	Very important

QMP3 The degree of training on any basic quality tools (flow diagrams, check sheets, histograms, scatter diagrams, control charts, Pareto analysis and fishbone diagrams, 5s's) in our organisation.

Little training	1	2	3	4	5	6	7	Much training

QMP4 The degree of shared responsibility in our organisation for the management of equipment. (Does each section/department only concern themselves with the proper functioning of their own equipment, or there a sense of shared responsibility for the organisation's equipment?)

Little sharing	1	2	3	4	5	6	7	Much sharing

QMP5 The extent to which risk management tools is an attribute of quality management practices in our organisation.

Little	1	2	3	4	5	6	7	Much

QMP6 The extent to which project management and planning tools are an attribute of quality management practices in my organisation.

Little	1	2	3	4	5	6	7	Much

QMP7 The extent to which a focus on waste reduction is a characteristic of the quality management practices in our organisation.

Little focus	1	2	3	4	5	6	7	Much focus

QMP8 The degree of importance attributed to incoming raw material inspection and validation.

Little	1	2	3	4	5	6	7	Much

QMP.9 The extent to which having a standardised system for supplier classification ensures uniform practices defining audit interval, scope, intensity and duration of supplier audits.

Little	1	2	3	4	5	6	7	Much

Section C Quality culture

QC1 In our organisation we have a shared "mind-set", or shared "set of values" about processes, systems, infrastructure and our organisation in general.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

Section C Quality Culture continues…

Annexure 6A Questionnaire Part 1 and Part 2 continued

Part 1 Page 3 of 4

Section C Quality Culture continued

QC2 Customer satisfaction is a priority at every level in our organisation (i.e. major component of everyone's job description), and it is clearly manifested just by talking to them or watching them work.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC3 Leadership of our organisation provides venues, time and resources for cross-functional training, quality training and team activities.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC4 Every person in our organisation understands what "quality work" is, and executes it every time.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC5 Our organisation monitors activity in order to identify non-value added activities and finds ways to reduce it.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC6 Quality is a super-ordinate value in the departments within our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC7 We respect internal customers in our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC8 We use customer feedback to establish if we have satisfied external customers in our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC9 Every person knows his/her contribution in attaining goals of the organisation and is prepared to handle the implications of not meeting them.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC10 Our organisation has a collaborative approach with suppliers.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC11 Top management of our organisation are involved (anything more than just simple awareness that it is taking place) with internal audits in our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC12 Reduced cycle times is a focus area that is shared by all departments in our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

QC13 Reduction in rejections (e.g. OOS, OOT, non-conforming documents and others) is a focus area that is shared by all departments in our organisation.

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

Section C Quality Culture continues…

QC14 Delivery reliability is a focus area that is shared by all departments in our organisation

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

Section D Organisation climate

OC1 The degree of alignment of our organisation's overall business strategy and the quality strategy of our organisation

Little alignment	1	2	3	4	5	6	7	Much alignment

Annexure 6A Questionnaire Part 1 and Part 2 continued

Part 1 Page 4 of 4

OC2 The degree to which sales focus (based on KPIs) in my organisation overrides quality management in my organisation.

Little conflict	1	2	3	4	5	6	7	Much conflict

OC3 Level of agility of my organisation's quality management practices with regard to external factors (How responsive is the quality department to organisational needs, e.g. document requirements, when an external factor such as a competitor threat presents itself?)

Little agility	1	2	3	4	5	6	7	Much agility

OC4 Level of agility of the entire organisation in response to a change in quality management requirements, e.g. regulatory requirement or continuous quality improvement initiative.

Little agility	1	2	3	4	5	6	7	Much agility

OC5 Aside from the regulated requirement of change control management, when a change is required by my organisation (business or quality management change such as significant budgetary change or staff movement), is it standard practice to conduct a risk or impact assessment for every change before a decision is taken to change?

Strongly Disagree	1	2	3	4	5	6	7	Strong Agree

OC6 The degree to which innovation in quality management practices is encouraged in my organisation to promote internal continuous improvement.

Little encouragement	1	2	3	4	5	6	7	Much encouragement

OC7 The degree to which innovation in quality management practices is encouraged in my organisation to promote external (customer/ MCC/ stakeholder) satisfaction.

Little encouragement	1	2	3	4	5	6	7	Much encouragement

OC8 The degree to which innovation is driven in my organisation by marketing requirements.

Little	1	2	3	4	5	6	7	Much

OC9 The degree to which innovation is driven in my organisation by research and development (R&D) requirements.

Little	1	2	3	4	5	6	7	Much

OC10 The degree to which innovation is driven in my organisation by pharmaceutical quality management system (PQMS) requirements.

Little	1	2	3	4	5	6	7	Much

Thank you very much for your time.

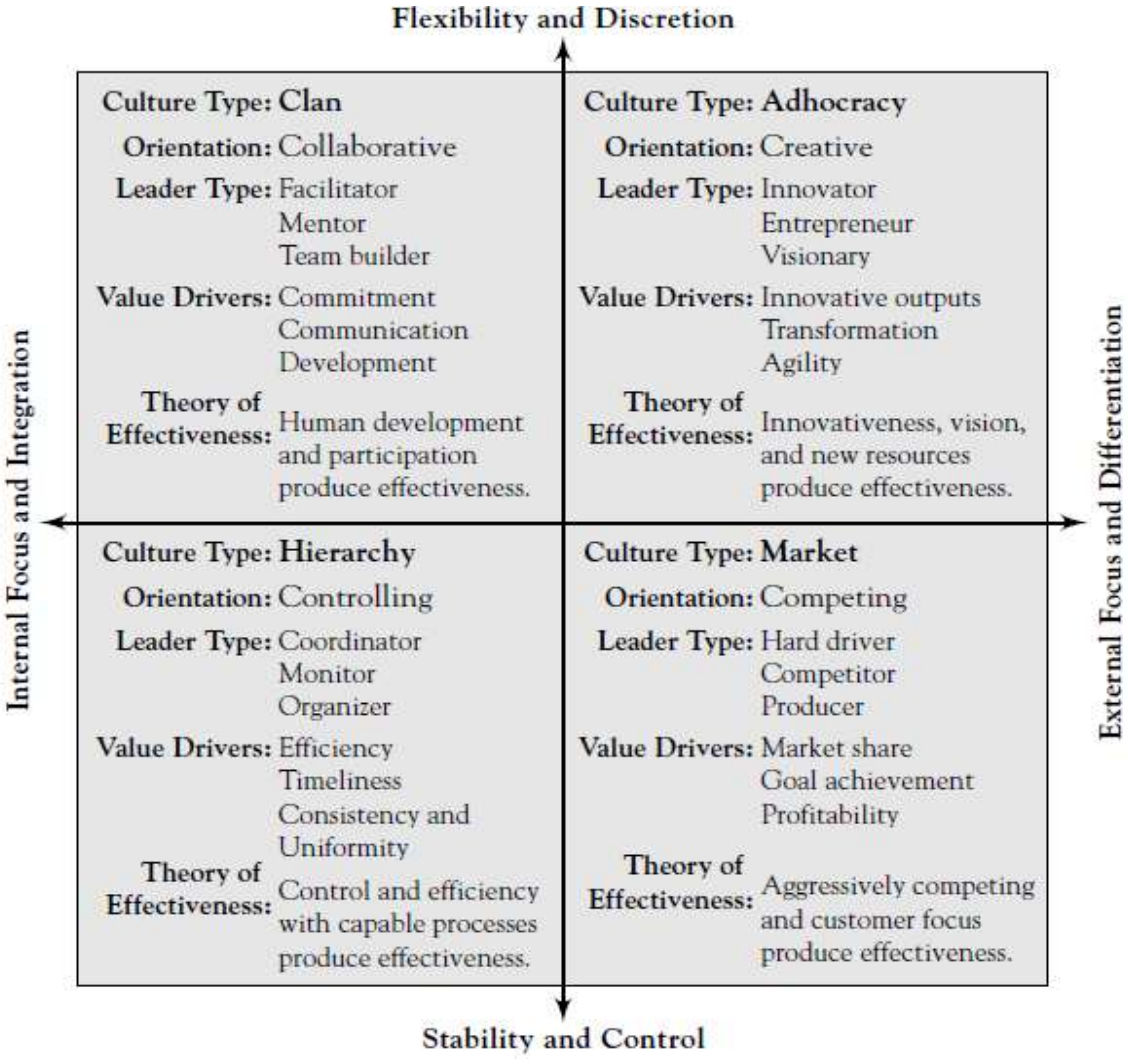
Annexure 6A Questionnaire Part 1 and Part 2 continued

Faculty of Management Sciences

Department of Public Management & Economics

Dear Pharmaceutical Manufacturer

This is an Organisational Culture Assessment Instrument (OCAI). The purpose of the OCAI is to assess your organisation's culture by considering the six key dimensions of organisational culture. The assessment is based on Cameron and Quinn (1999)'s 'Competing Values Framework', which was developed from research conducted on the major indicators of an effective organisation. The diagrammatic representation of the 'Competing Values Framework can be seen below. This information will be used to develop an Operational Excellence Model for pharmaceutical organisations in South Africa.



Annexure 6A Questionnaire Part 1 and Part 2 continued

Part 2 Page 2 of 3

The OCAI consists of 6 questions. Each question has four options. In total, each question accounts for a maximum amount of 100 points. Please divide the maximum allocation of 100 points for each question among the four options listed under that question, depending on the extent to which each alternative is similar to your organisation. Naturally, you will give the highest number of points to the option that is most similar to your organisation, and the least (or null) points to the option that is hardly similar or not at all like your organisation.

Question 1. Dominant Characteristics		
Option 1	The organisation is a very personal place. It is like an extended family. People seem to share a lot of themselves.	
Option 2	The organisation is a dynamic and entrepreneurial place. People are willing to stick their necks out and take risks.	
Option 3	The organisation is very results oriented. A major concern is with getting the job done. People are very competitive and achievement oriented.	
Option 4	The organisation is a very controlled and structured place. Formal procedures generally govern what people do.	
	Please double check your total adds up to 100 points	**100**

Question 2. Organisational Leadership		
Option 1	The leadership in the organisation is generally considered to exemplify mentoring, facilitating, or nurturing.	
Option 2	The leadership in the organisation is generally considered to exemplify entrepreneurship, innovation, or risk-taking.	
Option 3	The leadership in the organisation is generally considered to exemplify a no-nonsense, aggressive, results-oriented focus.	
Option 4	The leadership in the organisation is generally considered to exemplify coordinating, organizing, or smooth - running efficiency.	
	Please double check your total adds up to 100 points	**100**

Question 3. Management of Employees		
Option 1	The management style in the organisation is characterized by teamwork, consensus, and participation.	
Option 2	The management style in the organisation is characterized by individual risk taking, innovation, freedom, and uniqueness.	
Option 3	The management style in the organisation is characterized by hard-driving competitiveness, high demands, and achievement.	
Option 4	The management style in the organisation is characterized by security of employment, conformity, predictability, and stability in relationships.	
	Please double check your total adds up to 100 points	**100**

Annexure 6A Questionnaire Part 1 and Part 2 continued

Part 2 Page 3 of 3

Question 4. Organisation Glue		
Option 1	The glue that holds the organisation together is loyalty and mutual trust. Commitment to this organisation runs high.	
Option 2	The glue that holds the organisation together is commitment to innovation and development. There is an emphasis on being on the cutting edge.	
Option 3	The glue that holds the organisation together is the emphasis on achievement and goal accomplishment.	
Option 4	The glue that holds the organisation together is formal rules and policies. Maintaining a smoothly running organisation is important.	
	Please double check your total adds up to 100 points	**100**

Question 5. Strategic Emphases		
Option 1	The organisation emphasises human development. High trust, openness, and participation persist.	
Option 2	The organisation emphasises acquiring new resources and creating new challenges. Trying new things and prospecting for opportunities are valued.	
Option 3	The organisation emphasises competitive actions and achievement. Hitting stretch targets and winning in the marketplace are dominant.	
Option 4	The organisation emphasises permanence and stability. Efficiency, control, and smooth operations are important.	
	Please double check your total adds up to 100 points	**100**

Question 6. Criteria for success		
Option 1	The organisation defines success on the basis of the development of human resources, teamwork, employee commitment, and concern for people.	
Option 2	The organisation defines success on the basis of having unique or the newest products. It is a product leader and innovator.	
Option 3	The organisation defines success on the basis of winning in the marketplace and outpacing the competition. Competitive market leadership is key.	
Option 4	The organisation defines success on the basis of efficiency. Dependable delivery, smooth scheduling, and low - cost production is critical.	
	Please double check your total adds up to 100 points	**100**

Annexure 6B Reliability Analysis

Item-Total Statistics: Quality Management Practices				
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
QMP1	42.0909	58.829	0.647	0.900
QMP2	42.0455	58.277	0.651	0.900
QMP3	42.8636	52.772	0.774	0.891
QMP4	43.1591	53.672	0.748	0.893
QMP5	42.6591	54.881	0.837	0.886
QMP6	42.7273	54.342	0.868	0.883
QMP7	42.4545	57.882	0.719	0.895
QMP8	42.5455	64.998	0.628	0.913
QMP9	42.5455	66.347	0.680	0.909

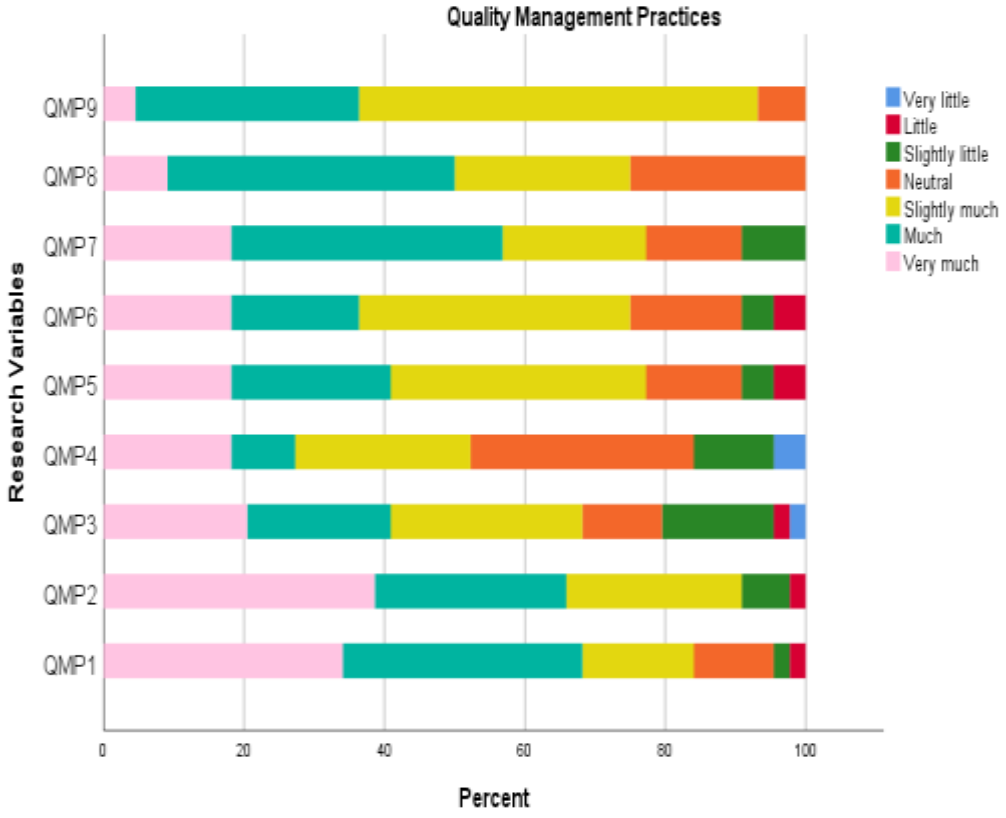
Item-Total Statistics Quality Culture				
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
QC 1	70.0227	226.069	0.823	0.949
QC 2	70.0682	226.251	0.827	0.949
QC 3	70.4318	229.832	0.698	0.952
QC 4	70.2727	232.715	0.777	0.950
QC 5	70.6591	220.928	0.822	0.949
QC 6	70.0455	228.463	0.793	0.950
QC 7	70.0682	224.112	0.829	0.949
QC 8	70.1364	231.330	0.633	0.954
QC 9	70.2955	226.771	0.798	0.949
QC 10	70.1136	231.871	0.724	0.951
QC 11	70.5682	230.995	0.582	0.955
QC 12	70.5227	224.162	0.792	0.950
QC 13	70.0000	230.093	0.733	0.951
QC 14	70.0682	224.484	0.775	0.950

Annexure 6B Reliability Analysis continued

Item-Total Quality Climate				
	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
OC 1	35.7045	69.515	0.725	0.880
OC 2	36.3864	76.615	0.602	0.926
OC 3	35.9545	66.091	0.726	0.877
OC 4	35.9545	65.579	0.761	0.874
OC 5	36.2500	66.936	0.602	0.889
OC 6	36.1818	61.315	0.902	0.859
OC 7	35.8864	62.196	0.835	0.865
OC 8	36.1746	64.984	0.654	0.886
OC 9	36.0418	61.991	0.711	0.849
OC 10	36.1136	60.522	0.773	0.871

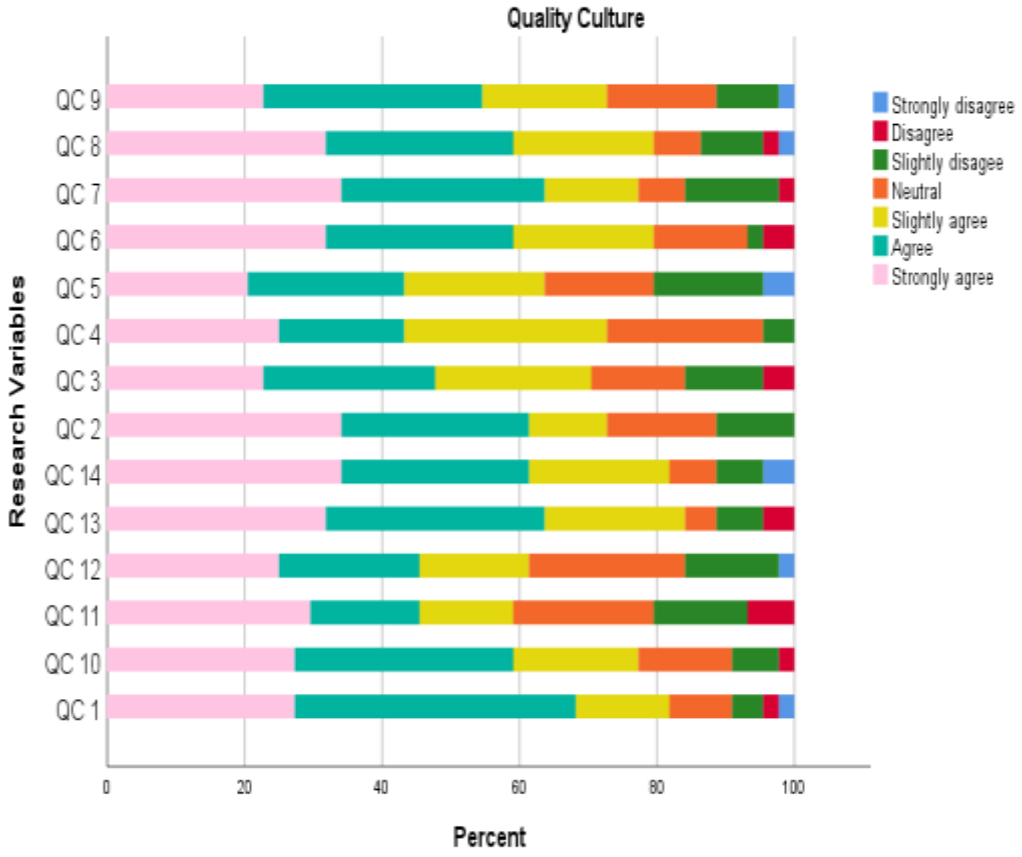
Annexure 6C Univariate graphs

Section B Quality Management Practices



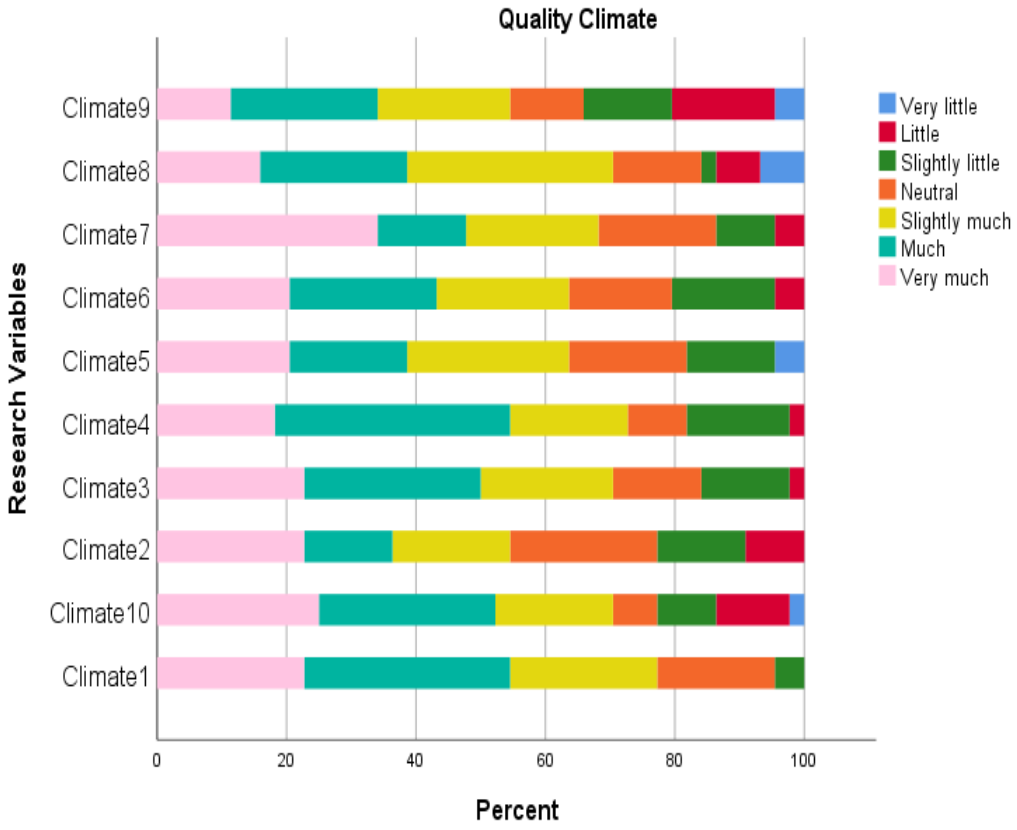
Annexure 6C – Univariate graphs continued

Section C Quality Culture



Annexure 6C – Univariate graphs continued

Section D Quality Climate



Annexure 6D Chi-square Frequencies

Section B Quality Management Practices Chi-Square Test Frequencies

Chi-Square Test Frequencies QMP1			
	Observed N	Expected N	Residual
Disagree	2	14.7	-12.7
Neutral	5	14.7	-9.7
Agree	37	14.7	22.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section B Quality Management Practices Chi-Square Test Frequencies

Chi-Square Test Frequencies QMP2			
	Observed N	Expected N	Residual
Disagree	4	22.0	-18.0
Agree	40	22.0	18.0
Total	44		

Chi-Square Test Frequencies QMP3			
	Observed N	Expected N	Residual
Disagree	9	14.7	-5.7
Neutral	5	14.7	-9.7
Agree	30	14.7	15.3
Total	44		

Chi-Square Test Frequencies QMP4			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	14	14.7	-.7
Agree	23	14.7	8.3
Total	44		

Chi-Square Test Frequencies QMP5			
	Observed N	Expected N	Residual
Disagree	4	14.7	-10.7
Neutral	6	14.7	-8.7
Agree	34	14.7	19.3
\Total	44		

Chi-Square Test Frequencies QMP6			
	Observed N	Expected N	Residual
Disagree	4	14.7	-10.7
Neutral	7	14.7	-7.7
Agree	33	14.7	18.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section B Quality Management Practices Chi-Square Test Frequencies

Chi-Square Test Frequencies QMP7			
	Observed N	Expected N	Residual
Disagree	4	14.7	-10.7
Neutral	6	14.7	-8.7
Agree	34	14.7	19.3
Total	44		

Chi-Square Test Frequencies QMP8			
	Observed N	Expected N	Residual
Neutral	11	22.0	-11.0
Agree	33	22.0	11.0
Total	44		

Chi-Square Test Frequencies QMP9			
	Observed N	Expected N	Residual
Neutral	3	22.0	-19.0
Agree	41	22.0	19.0
Total	44		

Section C Quality Culture Chi-Square Test Frequencies

Chi-Square Test Frequencies QC1			
	Observed N	Expected N	Residual
Disagree	4	14.7	-10.7
Neutral	4	14.7	-10.7
Agree	36	14.7	21.3
Total	44		

Chi-Square Test Frequencies QC2			
	Observed N	Expected N	Residual
Disagree	5	14.7	-9.7
Neutral	7	14.7	-7.7
Agree	32	14.7	17.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section C Quality Culture Chi-Square Test Frequencies

Chi-Square Test Frequencies QC3			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	6	14.7	-8.7
Agree	31	14.7	16.3
Total	44		

Chi-Square Test Frequencies QC4			
	Observed N	Expected N	Residual
Disagree	2	14.7	-12.7
Neutral	10	14.7	-4.7
Agree	32	14.7	17.3
Total	44		

Chi-Square Test Frequencies QC5			
	Observed N	Expected N	Residual
Disagree	9	14.7	-5.7
Neutral	5	14.7	-9.7
Agree	30	14.7	15.3
Total	44		

Chi-Square Test Frequencies QC6			
	Observed N	Expected N	Residual
Disagree	3	14.7	-11.7
Neutral	6	14.7	-8.7
Agree	35	14.7	20.3
Total	44		

Chi-Square Test Frequencies QC7			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	3	14.7	-11.7
Agree	34	14.7	19.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section C Quality Culture Chi-Square Test Frequencies

Chi-Square Test Frequencies QC8			
	Observed N	Expected N	Residual
Disagree	6	14.7	-8.7
Neutral	3	14.7	-11.7
Agree	35	14.7	20.3
Total	44		

Chi-Square Test Frequencies QC9			
	Observed N	Expected N	Residual
Disagree	5	14.7	-9.7
Neutral	7	14.7	-7.7
Agree	32	14.7	17.3
Total	44		

Chi-Square Test Frequencies QC10			
	Observed N	Expected N	Residual
Disagree	4	14.7	-10.7
Neutral	6	14.7	-8.7
Agree	34	14.7	19.3
Total	44		

Chi-Square Test Frequencies QC11			
	Observed N	Expected N	Residual
Disagree	9	14.7	-5.7
Neutral	9	14.7	-5.7
Agree	26	14.7	11.3
Total	44		

Chi-Square Test Frequencies QC12			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	10	14.7	-4.7
Agree	27	14.7	12.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section C Quality Culture Chi-Square Test Frequencies

Chi-Square Test Frequencies QC13			
	Observed N	Expected N	Residual
Disagree	5	14.7	-9.7
Neutral	2	14.7	-12.7
Agree	37	14.7	22.3
Total	44		

Chi-Square Test Frequencies QC14			
	Observed N	Expected N	Residual
Disagree	5	14.7	-9.7
Neutral	3	14.7	-11.7
Agree	36	14.7	21.3
Total	44		

Section D Quality Climate Chi-Square Test Frequencies

Chi-Square Test Frequencies OC1			
	Observed N	Expected N	Residual
Disagree	2	14.7	-12.7
Neutral	8	14.7	-6.7
Agree	34	14.7	19.3
Total	44		

Chi-Square Test Frequencies OC2			
	Observed N	Expected N	Residual
Disagree	10	14.7	-4.7
Neutral	10	14.7	-4.7
Agree	24	14.7	9.3
Total	44		

Chi-Square Test Frequencies OC3			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	6	14.7	-8.7
Agree	31	14.7	16.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section D Quality Climate Chi-Square Test Frequencies

Chi-Square Test Frequencies OC4			
	Observed N	Expected N	Residual
Disagree	8	14.7	-6.7
Neutral	2	14.7	-12.7
Agree	34	14.7	19.3
Total	44		

Chi-Square Test Frequencies OC5			
	Observed N	Expected N	Residual
Disagree	8	14.7	-6.7
Neutral	8	14.7	-6.7
Agree	28	14.7	13.3
Total	44		

Chi-Square Test Frequencies OC6			
	Observed N	Expected N	Residual
Disagree	9	14.7	-5.7
Neutral	7	14.7	-7.7
Agree	28	14.7	13.3
Total	44		

Chi-Square Test Frequencies OC7			
	Observed N	Expected N	Residual
Disagree	6	14.7	-8.7
Neutral	8	14.7	-6.7
Agree	30	14.7	15.3
Total	44		

Chi-Square Test Frequencies OC8			
	Observed N	Expected N	Residual
Disagree	7	14.7	-7.7
Neutral	6	14.7	-8.7
Agree	31	14.7	16.3
Total	44		

Annexure 6D Chi-square Frequencies continued

Section D Quality Climate Chi-Square Test Frequencies

Chi-Square Test Frequencies OC9			
	Observed N	Expected N	Residual
Disagree	15	14.7	0.3
Neutral	5	14.7	-9.7
Agree	24	14.7	9.3
Total	44		

Chi-Square Test Frequencies OC10			
	Observed N	Expected N	Residual
Disagree	10	14.7	-4.7
Neutral	3	14.7	-11.7
Agree	31	14.7	16.3
Total	44		

Chi Square Test Statistics			
	Chi-Square	df	Asymp. Sig.
Section B Quality Management Practices			
QMP1	51.318[a]	2	0.000
QMP2	29.455[b]	1	0.000
QMP3	24.591[a]	2	0.000
QMP4	8.773[a]	2	0.012
QMP5	38.364[a]	2	0.000
QMP6	34.682[a]	2	0.000
QMP7	38.364[a]	2	0.000
QMP8	11.000[b]	1	0.001
QMP9	32.818[b]	1	0.000
Section C Quality Culture			
QC1	46.545[a]	2	0.000
QC2	30.864[a]	2	0.000
QC3	27.318[a]	2	0.000
QC4	32.909[a]	2	0.000
QC5	24.591[a]	2	0.000
QC6	42.591[a]	2	0.000
QC7	38.773[a]	2	0.000
QC8	42.591[a]	2	0.000
QC9	30.864[a]	2	0.000
QC10	38.364[a]	2	0.000
QC11	13.136[a]	2	0.001

QC12	15.864[a]	2	0.000
QC13	51.318[a]	2	0.000
QC14	46.682[a]	2	0.000
Section D Quality Climate			
OC1	39.455[a]	2	0.000
OC2	8.909[a]	2	0.012
OC3	27.318[a]	2	0.000
OC4	39.455[a]	2	0.000
OC5	18.182[a]	2	0.000
OC6	18.318[a]	2	0.000
OC7	24.182[a]	2	0.000
OC8	27.318[a]	2	0.000
OC9	12.318[a]	2	0.002
OC10	28.955[a]	2	0.000
a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 14.7.			
b. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 22.0.			

For variables QMP2, QMP8 and QMP9 there were no neutral responses, this DF is 1.

Annexure 6E Spearman's Rho Correlations for all research variables in Part One of Questionnaire

		Column 1 QMP1	Column 2 QMP2	Column 3 QMP3	Column 4 QMP4	Column 5 QMP5	Column 6 QMP6	Column 7 QMP7	Column 8 QMP8	Column 9 QMP9
		Positive perception quality management	**Prescribed quality management practices**	**Training quality tools**	**Shared responsibility of equipment**	**Active risk management**	**Active project management**	**Active waste reduction**	**Active incoming material inspection**	**Uniformity promotes quality**
Row 1 QC1	**Shared mindset**	0.618**	0.494**	0.415**	0.580**	0.553**	0.482**	0.531**	0.116	0.190
Row 2 QC2	**Customer satisfaction priority**	0.624**	0.575**	0.507**	0.670**	0.429**	0.526**	0.472**	0.109	0.343*
Row 3 QC3	**Leadership support**	0.649**	0.432**	0.579**	0.427**	0.535**	0.602**	0.477**	0.361*	0.333*
Row 4 QC4	**Understanding of quality**	0.602**	0.517**	0.630**	0.533**	0.570**	0.647**	0.492**	0.143	0.320*
Row 5 QC5	**Eliminate non-value adding activities**	0.563**	0.464**	0.531**	0.587**	0.564**	0.508**	0.599**	0.251	0.211
Row 6 QC6	**Quality superordinate**	0.525	0.610	0.580	0.771	0.610	0.561	0.624	0.362	0.387
Row 7 QC7	**Internal customer respected**	0.523**	0.395**	0.494**	0.525**	0.545**	0.450**	0.454**	0.199	0.197

** significant at 0.01 (two-tailed) * significant at 0.05 (two-tailed)

		Column 1 QMP1	Column 2 QMP2	Column 3 QMP3	Column 4 QMP4	Column 5 QMP5	Column 6 QMP6	Column 7 QMP7	Column 8 QMP8	Column 9 QMP9
		Positive perception quality management	**Prescribed quality management practices**	**Training quality tools**	**Shared responsibility of equipment**	**Active risk management**	**Active project management**	**Active waste reduction**	**Active incoming material inspection**	**Uniformity promotes quality**
Row 8 QC8	**Customer feedback used**	0.553**	0.235	0.475**	0.344*	0.407**	0.489**	0.323*	0.394**	0.485**
Row 9 QC9	**Self-awareness about contribution**	0.484**	0.459**	0.453**	0.522**	0.495**	0.472**	0.515**	0.175	0.168
Row 10 QC10	**Collaborative suppliers**	0.419**	0.247	0.183	0.405**	0.428**	0.276	0.396**	0.337*	0.301*
Row 11 QC11	**Present leadership**	0.654**	0.377*	0.687**	0.561**	0.566**	0.612**	0.587**	0.285	0.449**
Row 12 QC12	**Reduced cycle times**	0.609**	0.492**	0.433**	0.633**	0.603**	0.292	0.664**	0.292	0.319*
Row 13 QC13	**Reduced rejections**	0.599**	0.697**	0.575**	0.671**	0.701**	0.729**	0.674**	0.183	0.351*
Row 14 QC14	**Delivery reliability**	0.749**	0.664**	0.593**	0.736**	0.643**	0.656**	0.708**	0.240	0.375*
Row 15 OC1	**Strategy and quality aligned**	0.756**	0.625**	0.668**	0.442**	0.613**	0.627**	0.599**	0.227	0.303*

** significant at 0.01 (two-tailed) * significant at 0.05 (two-tailed)

		Column 1 QMP1	Column 2 QMP2	Column 3 QMP3	Column 4 QMP4	Column 5 QMP5	Column 6 QMP6	Column 7 QMP7	Column 8 QMP8	Column 9 QMP9
		Positive perception quality management	**Prescribed quality management practices**	**Training quality tools**	**Shared responsibility of equipment**	**Active risk management**	**Active project management**	**Active waste reduction**	**Active incoming material inspection**	**Uniformity promotes quality**
Row 16 OC2	**Sales overrides quality**	0.368*	0.431**	0.052	0.168	0.339*	0.247	0.366*	0.048	0.147
Row 17 OC3	**Agile quality management**	0.535**	0.339*	0.437**	0.417**	0.522**	0.395**	0.547**	0.348*	0.255
Row 18 OC4	**Agile in response to external factors**	0.547**	0.529**	0.628**	0.624**	0.681**	0.592**	0.767**	0.341*	0.354*
Row 19 OC5	**Routine risk management**	0.541**	0.435**	0.525**	0.581**	0.571**	0.526**	0.576**	0.299*	0.205
Row 20 OC6	**Innovative continual improvement**	0.658**	0.522**	0.658**	0.628**	0.819**	0.696**	0.736**	0.420**	0.406**
Row 21 OC7	**Innovation for customer satisfaction**	0.434**	0.389**	0.500**	0.627**	0.686**	0.510**	0.646**	0.481**	0.299*
Row 22 OC8	**Innovation due to market requirements**	0.425**	0.302*	0.242	0.261	0.414**	0.266	0.463**	0.131	-0.033

** significant at 0.01 (two -ailed)

* significant at 0.05 (two-tailed)

		Column 1 QMP1	Column 2 QMP2	Column 3 QMP3	Column 4 QMP4	Column 5 QMP5	Column 6 QMP6	Column 7 QMP7	Column 8 QMP8	Column 9 QMP9
		Positive perception quality management	**Prescribed quality management practices**	**Training quality tools**	**Shared responsibility of equipment**	**Active risk management**	**Active project management**	**Active waste reduction**	**Active incoming material inspection**	**Uniformity promotes quality**
Row 23 OC9	**Innovation due to R&D**	0.367*	0.322*	0.434**	0.526**	0.528**	0.359*	0.681**	0.174	0.085
Row 24 OC10	**Innovation due to quality management requirements**	0.666**	0.465**	0.544**	0.612**	0.654**	0.551**	0.533**	0.229	0.253

** significant at 0.01 (two-tailed) * significant at 0.05 (two-tailed)

Annexure 6F Normality Test for Latent Variables and Regression Model Development

Descriptives				
			Statistic	Std. Error
Section B Quality Management Practices				
QMP	Mean		5.3207	0.14269
	95% Confidence Interval for Mean	Lower Bound	5.0329	
		Upper Bound	5.6085	
	Median		5.4444	
	Variance		0.896	
	Std. Deviation		.94652	
	Minimum		3.33	
	Maximum		6.78	
	Range		3.44	
	Interquartile Range		1.36	
	Skewness		-0.403	0.357
	Kurtosis		-0.467	0.702
Section C Quality Culture				
QC	Mean		5.4026	0.17469
	95% Confidence Interval for Mean	Lower Bound	5.0503	
		Upper Bound	5.7549	
	Median		5.6429	
	Variance		1.343	
	Std. Deviation		1.15874	
	Minimum		2.64	
	Maximum		6.93	
	Range		4.29	
	Interquartile Range		1.95	
	Skewness		-0.601	0.357
	Kurtosis		-0.493	0.702
Section D Quality Climate				
OC	Mean		5.0625	0.18484
	95% Confidence Interval for Mean	Lower Bound	4.6897	
		Upper Bound	5.4353	
	Median		5.2500	
	Variance		1.503	
	Std. Deviation		1.22608	
	Minimum		2.63	
	Maximum		7.00	
	Range		4.38	
	Interquartile Range		1.88	
	Skewness		-0.277	0.357
	Kurtosis		-1.015	0.702

Annexure 6F Normality test for latent variables and Regression Model development continued

Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
QMP	0.097	44	0.200*	0.953	44	0.074
QC	0.119	44	0.131	0.941	44	0.026
OC	0.109	44	0.200*	0.952	44	0.063
*. This is a lower bound of the true significance.						
a. Lilliefors Significance Correction						

Coefficients[a]			
		Collinearity Statistics	
Model		Tolerance	VIF
1	OC	0.385	2.598
	QC	0.385	2.598
a. Dependent Variable: QMP			

Collinearity Diagnostics[a]						
				Variance Proportions		
Model	Dimension	Eigenvalue	Condition Index	(Constant)	OC	QC
1	1	2.960	1.000	0.00	0.00	0.00
	2	0.030	9.967	0.91	0.19	0.04
	3	0.010	17.053	0.08	0.81	0.95
a. Dependent Variable: QMP						

Annexure 6F Normality test for latent variables and Regression Model development continued

Linear Regression Model

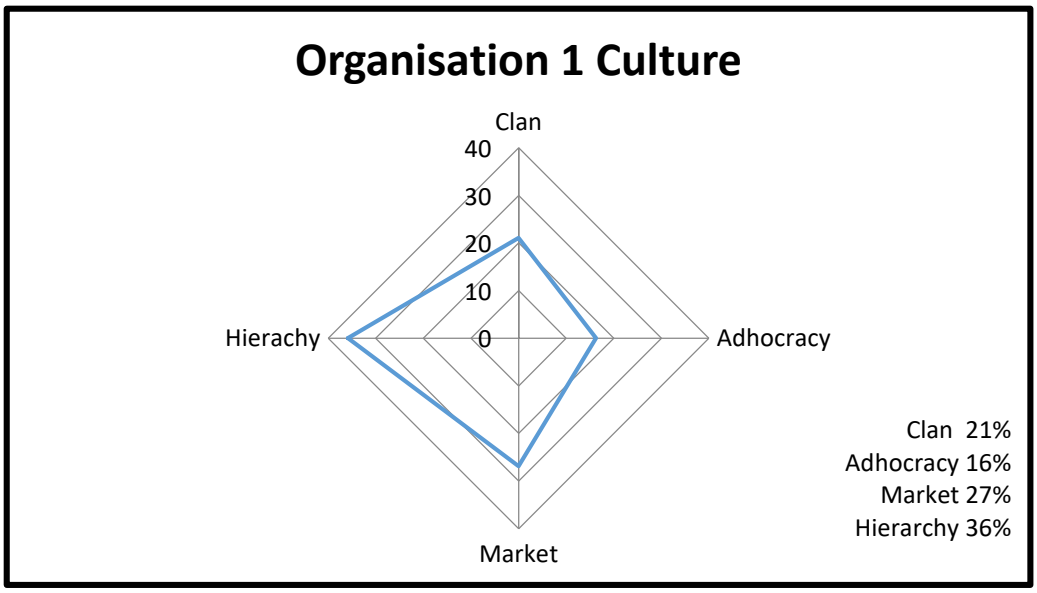
Variables Entered[a]			
Model	Variables Entered	Variables Removed	Method
1	OC, QC[b]	.	Enter
a. Dependent Variable: QMP			
b. All requested variables entered.			

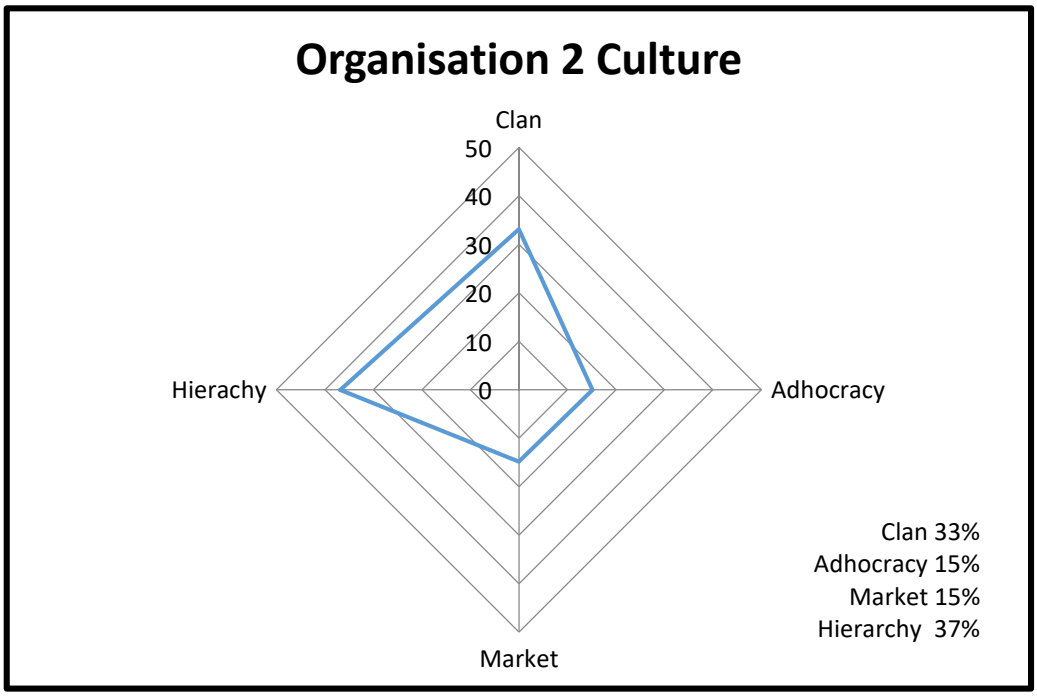
Model Summary				
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	0.825[a]	0.680	0.664	0.54825
a. Predictors: (Constant), OC, QC				

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	26.200	2	13.100	43.583	0.000[b]
	Residual	12.324	41	0.301		
	Total	38.524	43			
a. Dependent Variable: QMP						
b. Predictors: (Constant), OC, QC						

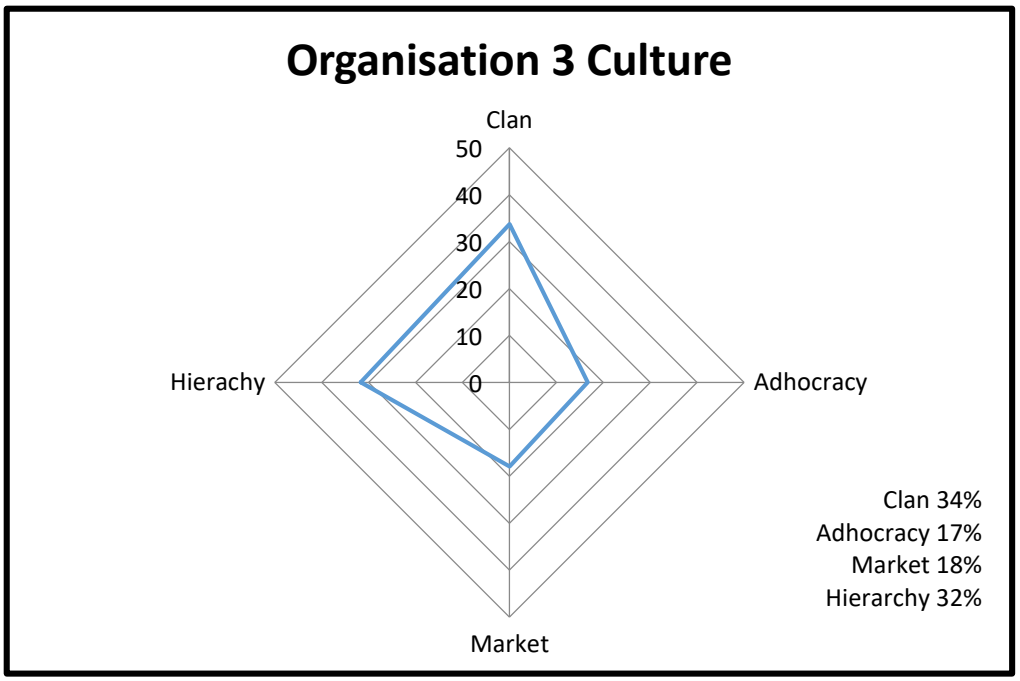
Coefficients[a]						
		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	1.679	0.404		4.161	0.000
	QC	.371	0.116	0.454	3.192	0.003
	OC	.323	0.110	0.419	2.940	0.005
a. Dependent Variable: QMP						

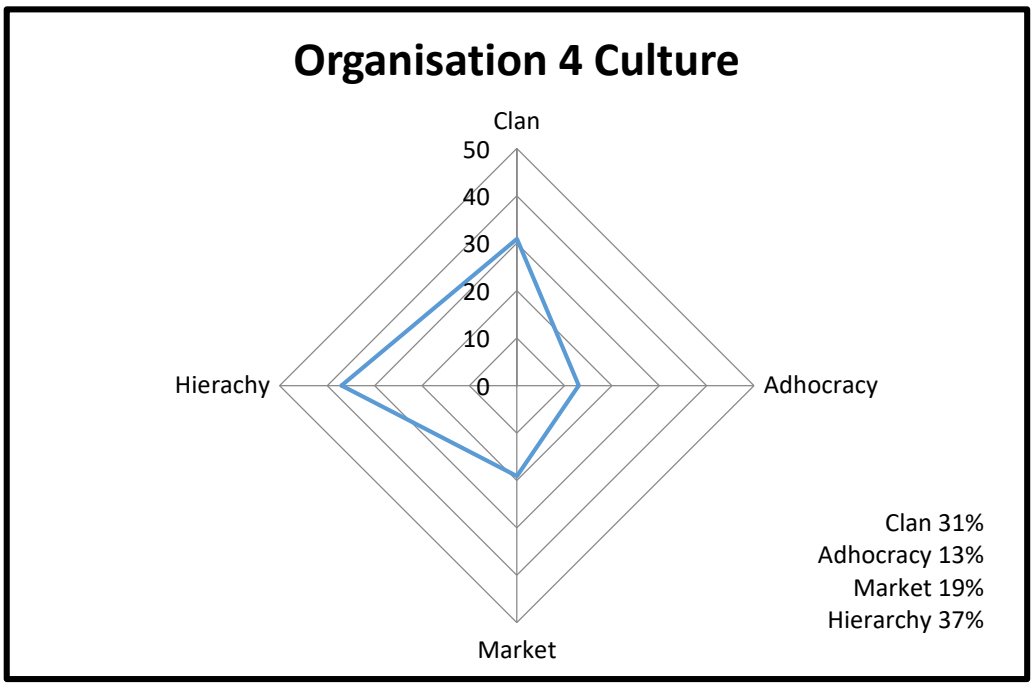
Annexure 6G The OCAI profile of all individual pharmaceutical organisations



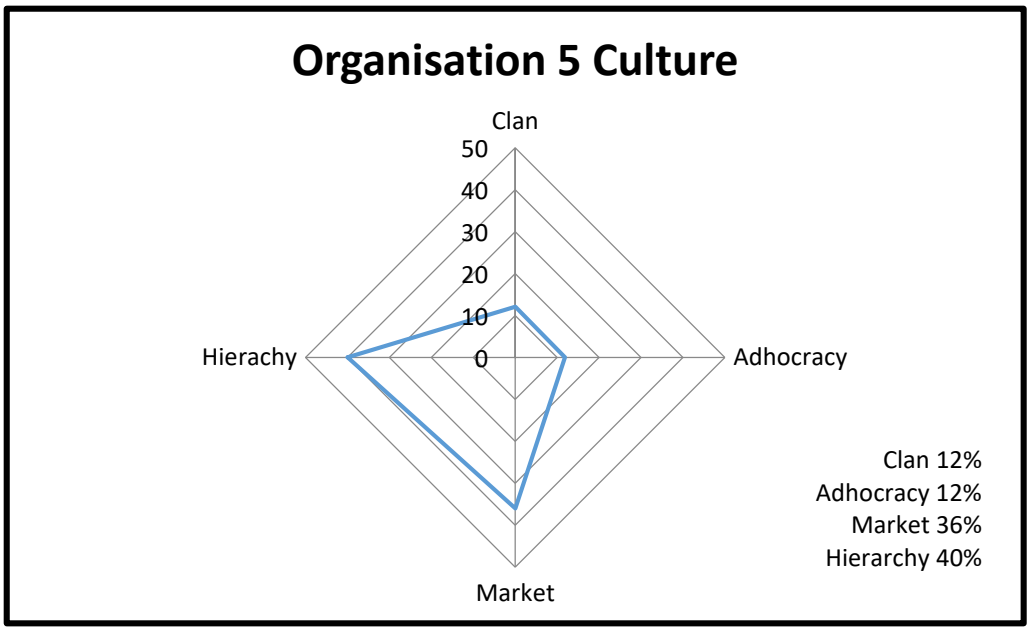


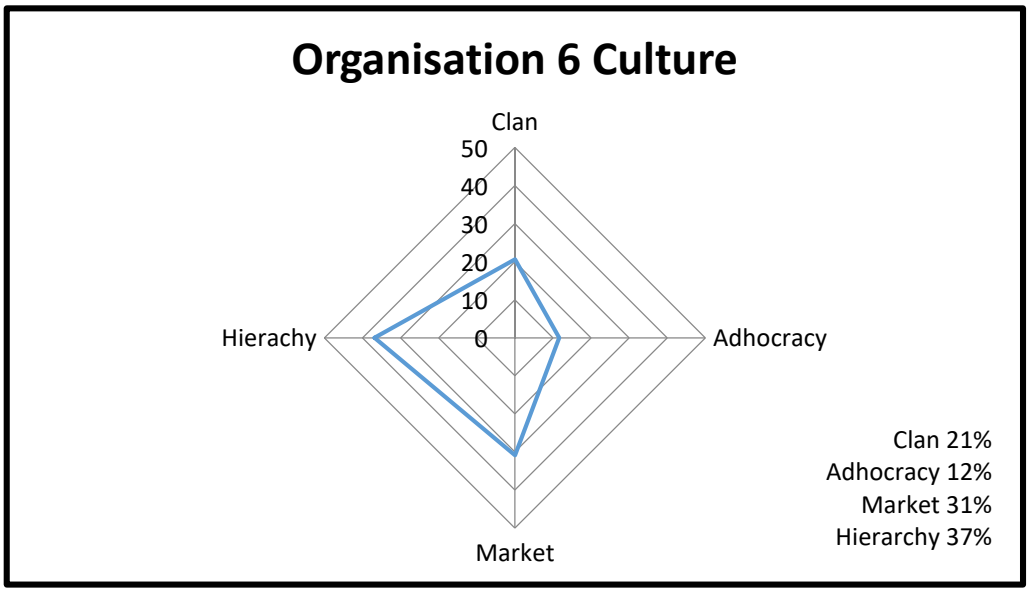
Annexure 6G The OCAI profile of all individual pharmaceutical organisations continued



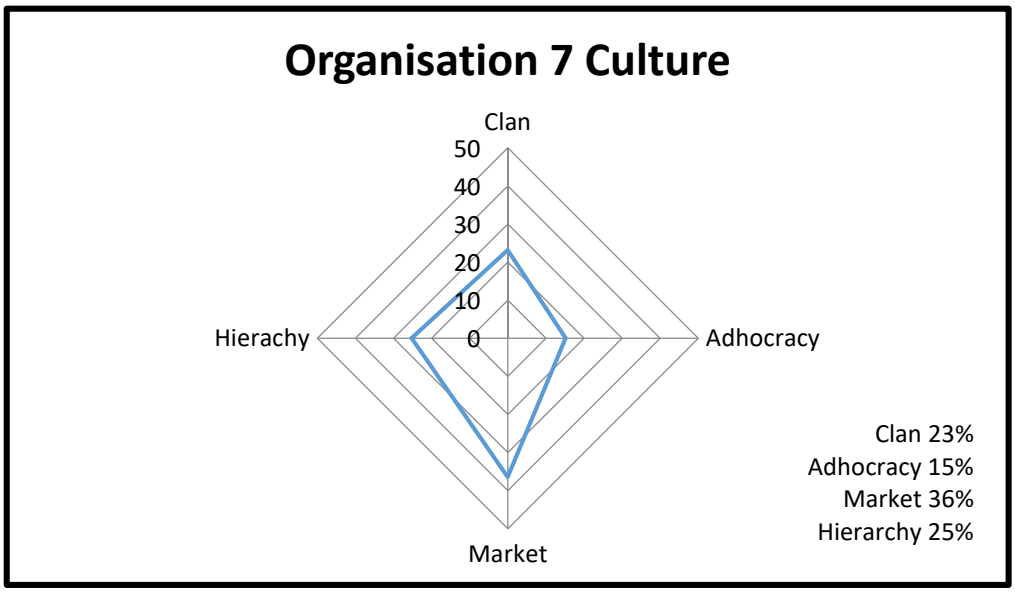


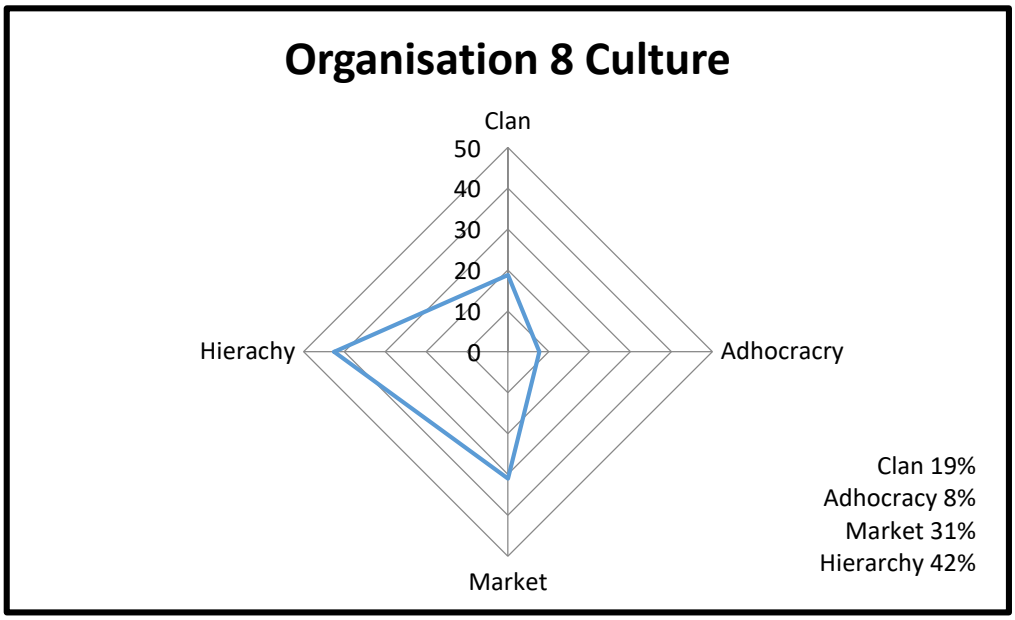
Annexure 6G The OCAI profile of all individual pharmaceutical organisations continued



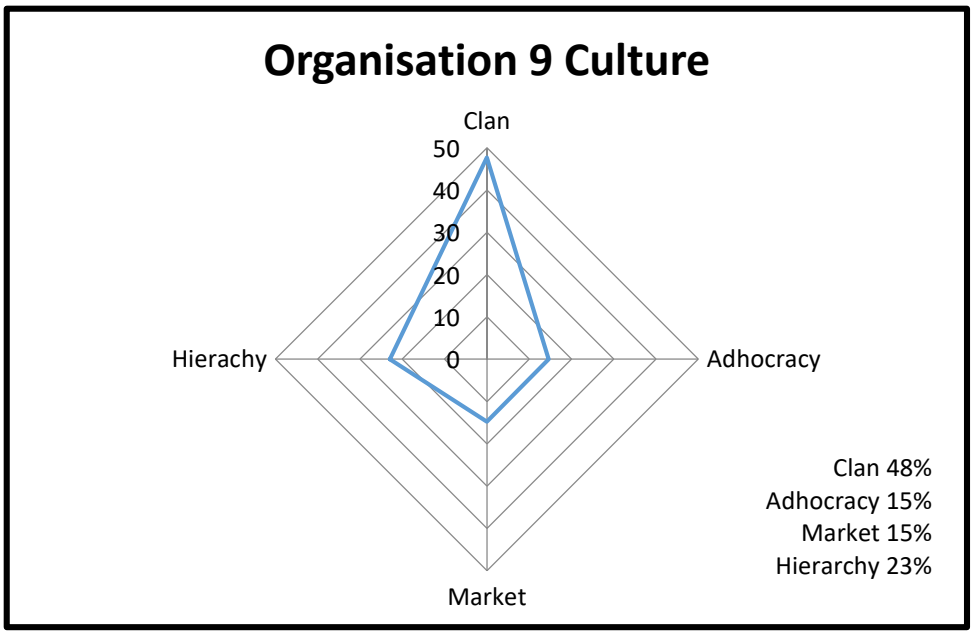


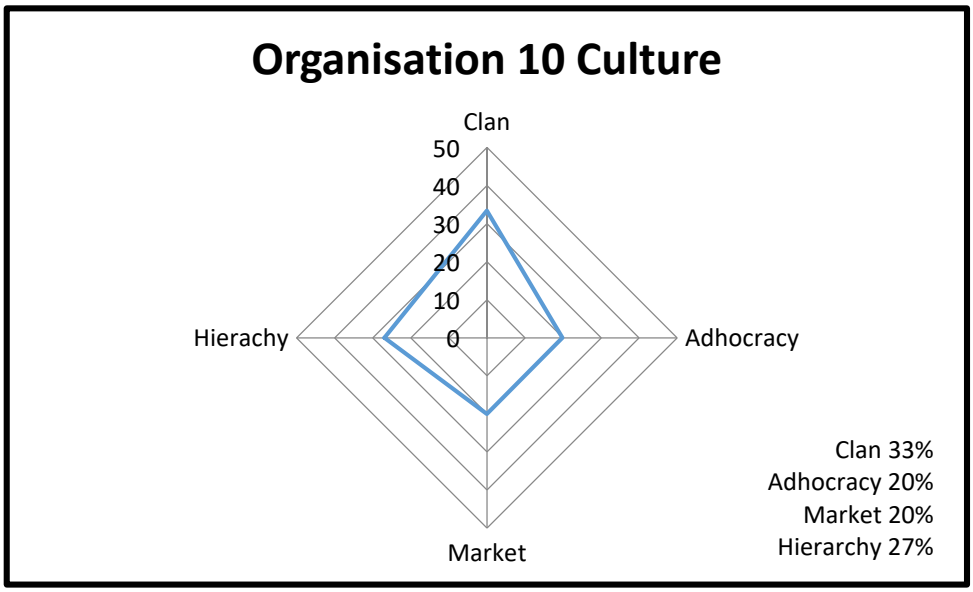
Annexure 6G The OCAI profile of all individual pharmaceutical organisations continued



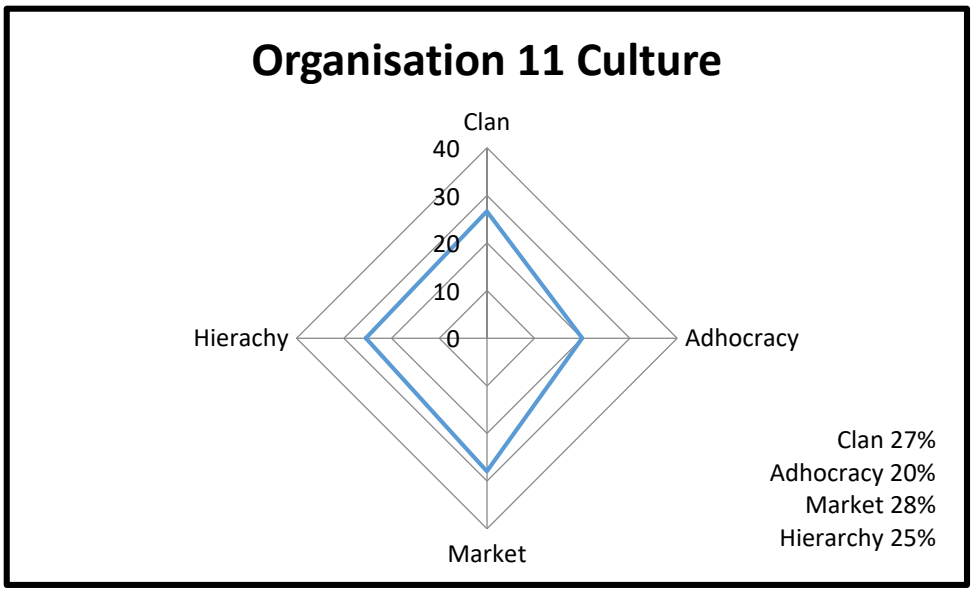


Annexure 6G The OCAI profile of all individual pharmaceutical organisations continued.





Annexure 6G The OCAI profile of all individual pharmaceutical organisations continued.



Annexure 6H One Factor ANOVA results for OCAI overall and each of the 6 variables and Tukey Kramer post-hoc test.

Descriptive stats of cultural traits presented below, obtained from 44 samples, therefore, it is appropriate to use ANOVA (Central Limit Theorem).

Analysis begins with Overall Cultural traits and thereafter traits of the 6 multidimensional variables are presented.

Descriptive Statistics		N	Mean	Std. Deviation	Std. Error	Minimum	Maximum
Overall	Clan	44	164.2614	89.40790	13.47875	0.00	450.00
	Adhocracy	44	88.3523	41.98194	6.32902	0.00	150.00
	Market	44	150.3977	66.08650	9.96291	0.00	300.00
	Hierarchy	44	196.9886	62.93818	9.48829	0.00	355.00
	Total	176	150.0000	77.49562	5.84145	0.00	450.00
Dominant Characteristics	Clan	44	21.3636	16.99397	2.56194	0.00	70.00
	Adhocracy	44	13.6364	10.58540	1.59581	0.00	30.00
	Market	44	22.3864	14.32548	2.15965	0.00	70.00
	Hierarchy	44	42.6136	24.50649	3.69449	0.00	100.00
	Total	176	25.0000	20.29778	1.53000	0.00	100.00
Organisational Leadership	Clan	44	28.6364	20.52689	3.09454	0.00	100.00
	Adhocracy	44	14.2045	9.01827	1.35956	0.00	30.00
	Market	44	26.3636	22.85861	3.44606	0.00	100.00
	Hierarchy	44	30.7955	15.95572	2.40542	0.00	60.00
	Total	176	25.0000	18.86796	1.42223	0.00	100.00
Employee Management	Clan	44	35.7955	19.07583	2.87579	0.00	100.00
	Adhocracy	44	13.6364	9.23615	1.39240	0.00	30.00
	Market	44	27.1591	17.79723	2.68303	0.00	70.00
	Hierarchy	44	23.4091	16.62769	2.50672	0.00	100.00
	Total	176	25.0000	17.88056	1.34780	0.00	100.00
Organisational Glue	Clan	44	24.6591	17.46750	2.63333	0.00	80.00
	Adhocracy	44	16.1364	16.09794	2.42686	0.00	100.00
	Market	44	20.7955	10.83401	1.63329	0.00	50.00
	Hierarchy	44	38.4091	20.84753	3.14288	0.00	100.00
	Total	176	25.0000	18.53953	1.39747	0.00	100.00
Strategic Emphasis	Clan	44	27.5568	19.37609	2.92106	0.00	100.00
	Adhocracy	44	15.8523	8.85843	1.33546	0.00	40.00
	Market	44	28.0114	18.91366	2.85134	0.00	100.00
	Hierarchy	44	28.5795	15.35811	2.31532	0.00	60.00
	Total	176	25.0000	16.89886	1.27380	0.00	100.00

Criteria For Success	Clan	44	26.2500	20.40648	3.07639	0.00	100.00
	Adhocracy	44	14.8864	10.31417	1.55492	0.00	50.00
	Market	44	25.6818	19.84214	2.99131	0.00	100.00
	Hierarchy	44	33.1818	17.78721	2.68152	0.00	70.00
	Total	176	25.0000	18.60108	1.40211	0.00	100.00

In the One Factor ANOVA test the p-value is 0.000, in each case thus the Null Hypothesis is rejected. The 4 groups (df in each n-1 thus 3) are not the same, therefore, the four culture types are not equally strong in South African pharmaceutical organisations. Follow up ANOVAs conducted on each of the individual variables indicate the same. For each of the different variables, namely Dominant characteristics, Organisational Leadership, Management of Employees, Organisational Glue, Strategic Emphasis and Criteria for Success, the four different culture types do not enjoy equal strength.

ANOVA

		Sum of Squares	df	Mean Square	F	Sig.
Overall	Between Groups	273324.432	3	91108.144	20.151	0.000
	Within Groups	777650.568	172	4521.224		
	Total	1050975.000	175			
Dominant Characteristics	Between Groups	20214.773	3	6738.258	22.337	0.000
	Within Groups	51885.227	172	301.658		
	Total	72100.000	175			
Organisational Leadership	Between Groups	7269.318	3	2423.106	7.573	0.000
	Within Groups	55030.682	172	319.946		
	Total	62300.000	175			
Employee Management	Between Groups	11126.136	3	3708.712	14.231	0.000
	Within Groups	44823.864	172	260.604		
	Total	55950.000	175			
Organisational Glue	Between Groups	12151.136	3	4050.379	14.514	0.000
	Within Groups	47998.864	172	279.063		
	Total	60150.000	175			
Strategic Emphasis	Between Groups	4932.386	3	1644.129	6.278	0.000
	Within Groups	45042.614	172	261.876		
	Total	49975.000	175			
Criteria For Success	Between Groups	7535.227	3	2511.742	8.149	0.000
	Within Groups	53014.773	172	308.225		
	Total	60550.000	175			

Annexure 6H One Factor ANOVA results for OCAI overall and each of the 6 variables and Tukey Kramer post-hoc test.

Tukey Kramer Post Hoc Tests

Dependent Variable	(I) CultureType	(J) CultureType	Mean Difference (I-J)	Std. Error	Sig.
Overall Quality Culture	Clan	Adhocracy	75.90909*	14.33563	0.000
		Market	13.86364	14.33563	0.768
		Hierarchy	-32.72727	14.33563	0.106
	Adhocracy	Clan	-75.90909*	14.33563	0.000
		Market	-62.04545*	14.33563	0.000
		Hierarchy	-108.63636*	14.33563	0.000
	Market	Clan	-13.86364	14.33563	0.768
		Adhocracy	62.04545*	14.33563	0.000
		Hierarchy	-46.59091*	14.33563	0.008
	Hierarchy	Clan	32.72727	14.33563	0.106
		Adhocracy	108.63636*	14.33563	0.000
		Market	46.59091*	14.33563	0.008

In terms of overall Quality Culture, the proportion of clan culture is statistically significantly different to the proportion of adhocracy culture. The proportion of adhocracy culture is statistically significantly different to the proportions of all other culture types. The proportion of market-driven culture is statistically significantly different to adhocracy and hierarchical culture but not clan culture. The proportion of hierarchical culture is statistically significantly different to market-driven culture and adhocracy culture but not clan culture.

Dominant Characteristics	Clan	Adhocracy	7.72727	3.70294	0.162
		Market	-1.02273	3.70294	0.993
		Hierarchy	-21.25000*	3.70294	0.000
	Adhocracy	Clan	-7.72727	3.70294	0.162
		Market	-8.75000	3.70294	0.088
		Hierarchy	-28.97727*	3.70294	0.000
	Market	Clan	1.02273	3.70294	0.993
		Adhocracy	8.75000	3.70294	0.088
		Hierarchy	-20.22727*	3.70294	0.000
	Hierarchy	Clan	21.25000*	3.70294	0.000
		Adhocracy	28.97727*	3.70294	0.000
		Market	20.22727*	3.70294	0.000

Annexure 6H One Factor ANOVA results for OCAI overall and each of the 6 variables and Tukey Kramer post-hoc test.

Tukey Kramer Post Hoc Tests

Organisational Leadership	Clan	Adhocracy	14.43182*	3.81353	0.001
		Market	2.27273	3.81353	0.933
		Hierarchy	-2.15909	3.81353	0.942
	Adhocracy	Clan	-14.43182*	3.81353	0.001
		Market	-12.15909*	3.81353	0.009
		Hierarchy	-16.59091*	3.81353	0.000
	Market	Clan	-2.27273	3.81353	0.933
		Adhocracy	12.15909*	3.81353	0.009
		Hierarchy	-4.43182	3.81353	0.652
	Hierarchy	Clan	2.15909	3.81353	0.942
		Adhocracy	16.59091*	3.81353	0.000
		Market	4.43182	3.81353	0.652

Employee Management	Clan	Adhocracy	22.15909*	3.44175	0.000
		Market	8.63636	3.44175	0.062
		Hierarchy	12.38636*	3.44175	0.002
	Adhocracy	Clan	-22.15909*	3.44175	0.000
		Market	-13.52273*	3.44175	0.001
		Hierarchy	-9.77273*	3.44175	0.026
	Market	Clan	-8.63636	3.44175	0.062
		Adhocracy	13.52273*	3.44175	0.001
		Hierarchy	3.75000	3.44175	0.696
	Hierarchy	Clan	-12.38636*	3.44175	0.002
		Adhocracy	9.77273*	3.44175	0.026
		Market	-3.75000	3.44175	0.696

Organisational Glue	Clan	Adhocracy	8.52273	3.56156	0.082
		Market	3.86364	3.56156	0.699
		Hierarchy	-13.75000*	3.56156	0.001
	Adhocracy	Clan	-8.52273	3.56156	0.082
		Market	-4.65909	3.56156	0.559
		Hierarchy	-22.27273*	3.56156	0.000
	Market	Clan	-3.86364	3.56156	0.699
		Adhocracy	4.65909	3.56156	0.559
		Hierarchy	-17.61364*	3.56156	0.000
	Hierarchy	Clan	13.75000*	3.56156	0.001
		Adhocracy	22.27273*	3.56156	0.000
		Market	17.61364*	3.56156	0.000

Annexure 6H One Factor ANOVA results for OCAI overall and each of the 6 variables and Tukey Kramer post-hoc test.

Tukey Kramer Post Hoc Tests

Strategic Emphasis	Clan	Adhocracy	11.70455*	3.45014	0.005
		Market	-.45455	3.45014	0.999
		Hierarchy	-1.02273	3.45014	0.991
	Adhocracy	Clan	-11.70455*	3.45014	0.005
		Market	-12.15909*	3.45014	0.003
		Hierarchy	-12.72727*	3.45014	0.002
	Market	Clan	.45455	3.45014	0.999
		Adhocracy	12.15909*	3.45014	0.003
		Hierarchy	-.56818	3.45014	0.998
	Hierarchy	Clan	1.02273	3.45014	0.991
		Adhocracy	12.72727*	3.45014	0.002
		Market	.56818	3.45014	0.998

Criteria For Success	Clan	Adhocracy	11.36364*	3.74303	0.015
		Market	.56818	3.74303	0.999
		Hierarchy	-6.93182	3.74303	0.253
	Adhocracy	Clan	-11.36364*	3.74303	0.015
		Market	-10.79545*	3.74303	0.023
		Hierarchy	-18.29545*	3.74303	0.000
	Market	Clan	-.56818	3.74303	0.999
		Adhocracy	10.79545*	3.74303	0.023
		Hierarchy	-7.50000	3.74303	0.191
	Hierarchy	Clan	6.93182	3.74303	0.253
		Adhocracy	18.29545*	3.74303	0.000
		Market	7.50000	3.74303	0.191

Annexure 6l – Spearman correlations comparing each dimension to each cultural trait.

Strategy			
Spearman's rho	Clan Type	Correlation Coefficient	0.423
		Sig. (2-tailed)	0.004
		N	44
	Adhocracy Type	Correlation Coefficient	0.384
		Sig. (2-tailed)	0.010
		N	44
	Market Type	Correlation Coefficient	-0.347
		Sig. (2-tailed)	0.021
		N	44
	Hierarchy Type	Correlation Coefficient	-0.423
		Sig. (2-tailed)	0.004
		N	44

Leadership			
Spearman's rho	Clan Type	Correlation Coefficient	0.515
		Sig. (2-tailed)	0.000
		N	44
	Adhocracy Type	Correlation Coefficient	0.408
		Sig. (2-tailed)	0.006
		N	44
	Market Type	Correlation Coefficient	-0.384
		Sig. (2-tailed)	0.010
		N	44
	Hierarchy Type	Correlation Coefficient	-0.468
		Sig. (2-tailed)	0.001
		N	44

Annexure 6I Spearman correlations comparing each dimension to each cultural trait continued.

Employee Empowerment			
Spearman's rho	Clan Type	Correlation Coefficient	0.510
		Sig. (2-tailed)	0.000
		N	44
	Adhocracy Type	Correlation Coefficient	0.354
		Sig. (2-tailed)	0.018
		N	44
	Market Type	Correlation Coefficient	-0.529
		Sig. (2-tailed)	0.000
		N	44
	Hierarchy Type	Correlation Coefficient	-0.395
		Sig. (2-tailed)	0.008
		N	44

Customer Focus			
Spearman's rho	Clan Type	Correlation Coefficient	0.442
		Sig. (2-tailed)	0.003
		N	44
	Adhocracy Type	Correlation Coefficient	0.415
		Sig. (2-tailed)	0.005
		N	44
	Market Type	Correlation Coefficient	0.486
		Sig. (2-tailed)	0.001
		N	44
	Hierarchy Type	Correlation Coefficient	0.357
		Sig. (2-tailed)	0.017
		N	44

Annexure 6I Spearman correlations comparing each dimension to each cultural trait continued.

Continual Improvement			
Spearman's rho	Clan Type	Correlation Coefficient	0.490
		Sig. (2-tailed)	0.001
		N	44
	Adhocracy Type	Correlation Coefficient	0.422
		Sig. (2-tailed)	0.004
		N	44
	Market Type	Correlation Coefficient	-0.433
		Sig. (2-tailed)	0.003
		N	44
	Hierarchy Type	Correlation Coefficient	-0.436
		Sig. (2-tailed)	0.003
		N	44

Supplier Management			
Spearman's rho	Clan Type	Correlation Coefficient	0.262
		Sig. (2-tailed)	0.086
		N	44
	Adhocracy Type	Correlation Coefficient	0.476
		Sig. (2-tailed)	0.001
		N	44
	Market Type	Correlation Coefficient	0.224
		Sig. (2-tailed)	0.143
		N	44
	Hierarchy Type	Correlation Coefficient	0.448
		Sig. (2-tailed)	0.002
		N	44

Annexure 6I Spearman correlations comparing each dimension to each cultural trait continued.

Systems Approach			
Spearman's rho	Clan Type	Correlation Coefficient	0.454
		Sig. (2-tailed)	0.002
		N	44
	Adhocracy Type	Correlation Coefficient	0.562
		Sig. (2-tailed)	0.000
		N	44
	Market Type	Correlation Coefficient	-0.494
		Sig. (2-tailed)	.001
		N	44
	Hierarchy Type	Correlation Coefficient	0.599
		Sig. (2-tailed)	.001
		N	44

Training and Agility			
Spearman's rho	Clan Type	Correlation Coefficient	0.504
		Sig. (2-tailed)	0.000
		N	44
	Adhocracy Type	Correlation Coefficient	0.411
		Sig. (2-tailed)	0.006
		N	44
	Market Type	Correlation Coefficient	-0.421
		Sig. (2-tailed)	0.004
		N	44
	Hierarchy Type	Correlation Coefficient	-0.499
		Sig. (2-tailed)	0.001
		N	44

Annexure 6I Spearman correlations comparing each dimension to each cultural trait continued.

Fact-based Management			
Spearman's rho	Clan Type	Correlation Coefficient	0.420
		Sig. (2-tailed)	0.005
		N	44
	Adhocracy Type	Correlation Coefficient	0.488
		Sig. (2-tailed)	0.001
		N	44
	Market Type	Correlation Coefficient	-0.433
		Sig. (2-tailed)	0.003
		N	44
	Hierarchy Type	Correlation Coefficient	0.497
		Sig. (2-tailed)	0.008
		N	44

Annexure 7A Confidentiality agreement and Interview Schedule

Letter to participants

TITLE OF THE STUDY AND RESEARCHER DETAILS:

An analysis of quality culture and quality management practices in selected South African pharmaceutical organisations

By Researcher: Bronwyn Claudia Swartz
Department of Industrial and Systems Engineering
CPUT Bellville Campus

Supervisor: Prof Shalini Singh

This research investigates factors that contribute to Operational Excellence (OpEx) in pharmaceutical manufacturing organisations, with specific focus on quality culture and the effect of quality culture on quality management practices.

Cameron and Quinn (1999)'s Organisational Culture Assessment Instrument (OCAI) seen in Figure 1 provided this research with a research lens. Data on perceptions of culture and quality management practices was collected from 57% of all the pharmaceutical manufacturers in South Africa. The most significant findings of data analysis were

- Quality management practices are influenced by quality culture
- Specific GMP quality management practices are tools in pharmaceutical organisations, which assist them to achieve success in nine dimensions of OpEx. These dimensions are Leadership, Employee Empowerment, Training and Agility, Customer Focus, Continual Improvement, Systems Approach, Strategy, Fact based Management and Supplier Management.
- Empirical evidence demonstrates that each of the OCAI culture types has distinctly different explanatory power over the different OpEx Dimensions and different GMP quality management practices. Research has used this information to develop the model depicted by Annexure 1 and Annexure 2.

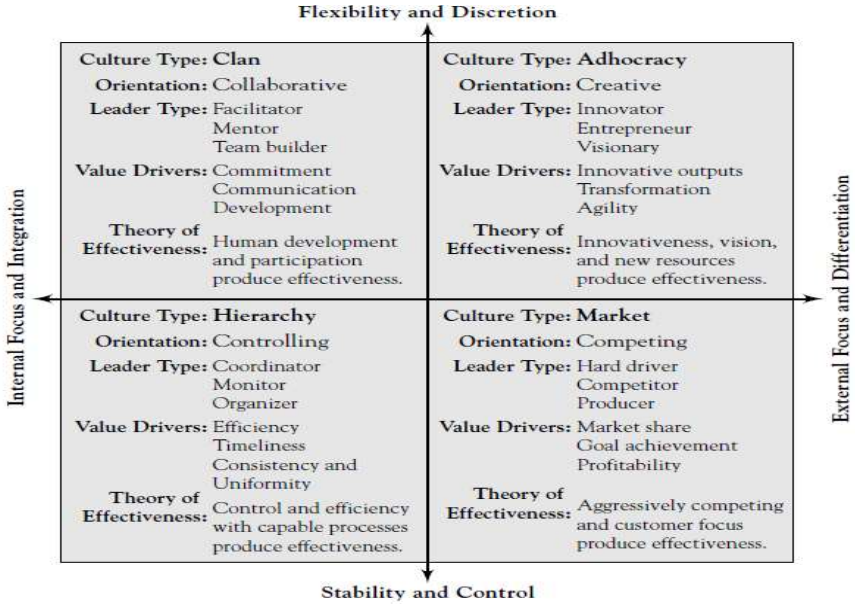


Figure 1: Four Different Culture Types

Annexure 7A continued: Confidentiality agreement and interview schedule

Dear Participant

You have been identified as an expert on quality management in the pharmaceutical industry, and therefore, requested to participate in a data collection interview. I believe that your input is extremely valuable. I assure your confidentiality, as explained below. Please consider the following:

1. You are requested to give data and permission to use data as an individual, not as a representative of any organisation or group;
2. Whether or not you give this permission is entirely your personal decision, and it is entirely voluntary;
3. There will be no rewards for giving this permission, as there will, of course, be no penalty for refusing it;
4. You have a right to withdraw your permission at any stage, and I will then exclude your data from this research;
5. I would like to use your contributions for the purpose of optimising a GMP model of practices for the pharmaceutical industry in South Africa for scholarly research and publication;
6. Confidentiality will be ensured through a number of mechanisms:
    - Pseudonyms or a numerical system (e.g. Participant 1, Participant 2, etc.) will be used when verbatim quotations are used for illustrative purposes in academic papers;
    - Background information that could make identification possible will not be included in any academic paper or public document.

This project has ethics clearance from the Durban University of Technology and permission has been granted for research activities to take place.

I do not agree to be interviewed ☐

I agree to be interviewed ☐

Full name (will not be disclosed in research study)_____

Capacity (will not be disclosed in research study)_____

Signature

_____

Annexure 7A continued: Confidentiality agreement and interview schedule

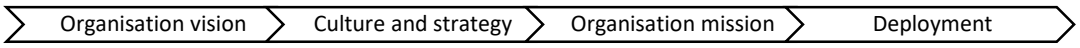
Interview Questions

Question 1

1.1 In consideration of Annexure 1 (General overview of the OpEx Model for pharmaceutical organisations in South Africa), would you agree or disagree that this is a suitable broad (high level) structure for an OpEx model?

Possible points to consider:

- This relationship below?:



- Should a Balance Scorecard be used?
- Are OpEx Dimensions representative of reality (and do KPIs lead to targets)?
- Do those Quality Management Practices represent reality (and do resources lead to results)?

1.2 Please elaborate (if you have not already in question 1.1) on why or why not you agree or disagree that this is a suitable broad (high level) structure for an OpEx Model for SA Pharma

Question 2

Still, with reference to Annexure 1, the dimensions of OpEx are referred to as critical success factors in the model. The research considers these interdependent factors to be critical for the success of OpEx

2.1 To you, does it look like anything (a factor) is here but should not be here?

2.2 Does it look like anything is missing?

2.3 In consideration of the culture types which were empirically found to have the greatest explanatory power over selected dimensions, would you like to comment on why or why not you agree with any of them?

Question 3

With reference to Annexure 2, research has identified what is considered to be the most important quality management practice to be operationally excellent in a GMP environment. Keeping in mind that this is simply a model, and therefore, not 100% representative of reality, research has found that:

- Selected quality management practices have a more significant effect on selected Opex Dimensions (critical success factors) than others…. And
- These practices and dimensions are supported by OCAI culture types

3.1 Can you comment on this, please?

Annexure 7A continued: Confidentiality agreement and interview schedule

Question 4

4.1 The proposed model (Annexure 1 and Annexure 2) has a strong foundation in literature and is supported by empirical evidence. Going forward from here, in your opinion, what does this model need to be valuable (or add value or be useful to your world)?

Possible points to consider:

- Does it add any value at all? If you do not regard it as useful, please explain why.
- Can a refined version of the research instrument be used for a gap analysis (current state of organisation and requirements for the desired state of organisation)?
- Do you think that with the conceptual model OpEx can be achieved in SA pharma organisations, through specific directives, for example, with the HR department (change management and training) to move an organisation to the desired state?

Question 5

Is there anything else that you would like research to consider?

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Thank you very much for your time !

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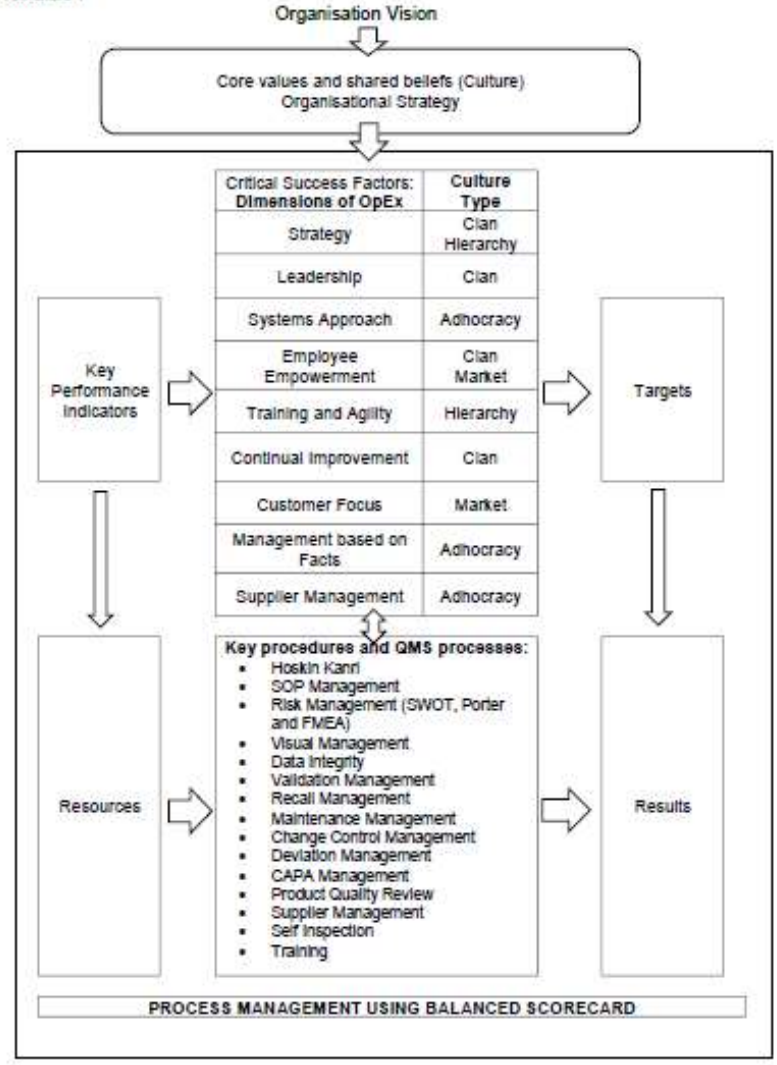
Annexure 7A continued: Confidentiality agreement and interview schedule (Proposed Model provided to research participants)

Annexure 1



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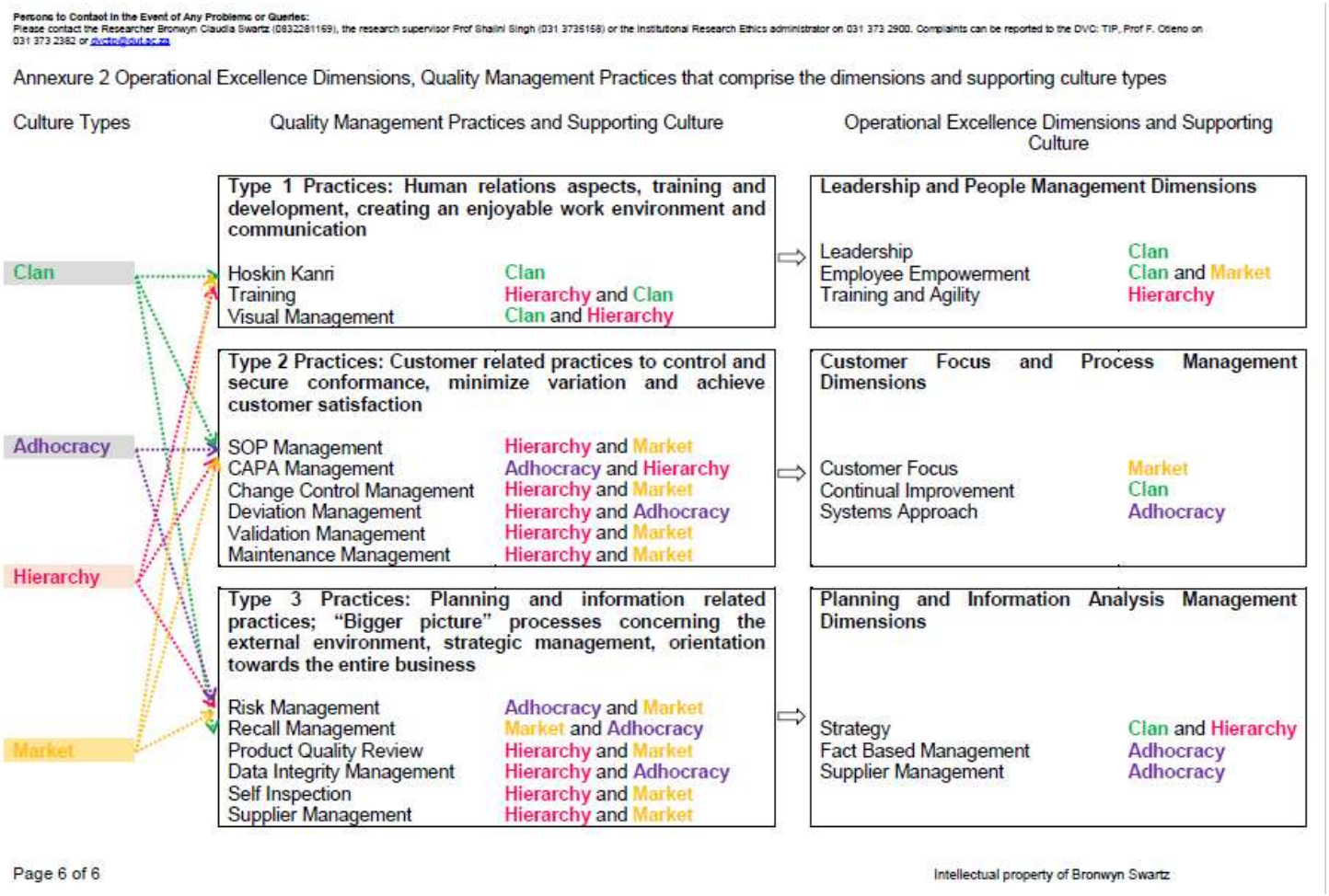
Annexure 7A continued: Confidentiality agreement and interview schedule (Proposed Model provided to research participants)



Persons to Contact in the Event of Any Problems or Queries:
Please contact the Researcher Bronwyn Claudia Swartz (0832281169), the research supervisor Prof Shalini Singh (031 3735158) or the Institutional Research Ethics administrator on 031 373 2900. Complaints can be reported to the DVC: TIP, Prof F. Otieno on 031 373 2382 or dvctip@dut.ac.za

Annexure 2 Operational Excellence Dimensions, Quality Management Practices that comprise the dimensions and supporting culture types

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